UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE GLAXOSMITHKLINE ERISA LITIGATION This Document Relates To: All Actions	1:10-cv-06419-AKH **CLASS ACTION** **JURY TRIAL DEMANDED**

CONSOLIDATED AMENDED COMPLAINT FOR VIOLATIONS OF THE EMPLOYEE RETIREMENT INCOME SECURITY ACT

Plaintiffs Charles J. Gum and Marilyn S. Hayes ("Plaintiffs"), on behalf of themselves and a class consisting of similarly situated participants and beneficiaries (the "Participants") of the GlaxoSmithKline Retirement Savings Plan (the "GSK Plan") and the GSK Puerto Rico Retirement Savings Plan (the "Puerto Rico Plan") (the GSK Plan and the Puerto Rico Plan are hereinafter referred to collectively as the "Plans"), by their attorneys, allege the following for their Consolidated Amended Complaint (the "Complaint"). The allegations contained herein are based on the investigation of counsel, except for those allegations pertaining to Plaintiffs, which are based on personal knowledge. Plaintiffs may, after discovery and/or disclosure proceedings in this case, seek leave to amend this Complaint to add new parties or claims.

NATURE OF ACTION

1. Plaintiffs, who were each Participants, as defined by ERISA §§ 3(7) and 502(a), 29 U.S.C. §§ 1102(7) and 1132(a), in at least one of the Plans during time periods relevant to this Complaint, bring this civil enforcement action under Section 502(a) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1132(a), for plan-wide relief on behalf of a class consisting of all current and former Participants in the Plans for whose individual accounts the Plans held American Depository Shares ("ADSs") of GlaxoSmithKline plc (hereinafter "GSK" or the "Company") (including in the form of units of the GSK Common Stock Fund (the "GSK Stock Fund" or the "Fund")) at any time from May 8, 2007 through November 9, 2010 (the "Class Period"). Plaintiffs bring this action on behalf of the Plans and the Class pursuant to § 502(a)(2) of ERISA, 29 U.S.C. § 1132(a)(2).

2. As more fully set forth below, Defendants breached their fiduciary duties to the Participants, including those fiduciary duties set forth in ERISA § 404, 29 U.S.C. § 1104, and Department of Labor Regulations, including 29 C.F.R. § 2550. Defendants breached their

fiduciary duties to the Participants in various ways, including, but not limited to: (i) misrepresenting and failing to disclose material facts to the Participants in connection with the administration of the Plans; (ii) failing to exercise their fiduciary duties to the Participants solely in the interests of the Participants for the exclusive purpose of providing benefits to Participants and their beneficiaries; (iii) failing to manage the Plans' assets with the care, skill, prudence or diligence of a prudent person under the circumstances; and (iv) permitting the Participants to continue to elect to invest their retirement monies in GSK ADSs when it was imprudent to do so, and when the Participants were not provided with timely, accurate and complete information concerning the Company as required by applicable law. As a result of these wrongful acts, pursuant to ERISA § 409(a), 29 U.S.C. § 1109(a), Defendants are personally liable to make good to the Plans the losses resulting from each such breach of fiduciary duty.

3. As set forth in further detail below, GSK ADSs were imprudent for the Participants' retirement savings, and Defendants, in violation of their ERISA fiduciary duties, failed to disclose that, *inter alia*:

a. the Company has a history of conducting misleading and/or unlawful business activity, both prior to and during the Class Period with regards to, *inter alia*, GSK's manufacturing, marketing and distributing of prescription medication;

b. the Company's Cidra, Puerto Rico plant was riddled with violations of federal rules and regulations with regards to the operation of that plant, which violations had a large and detrimental effect on, in particular, the Company's sale of Paxil and Paxil CR;

c. the Company had suppressed adverse studies relevant to use of Paxil to treat children and adolescents with depression;

d. the Company had suppressed patient-level meta-analysis of safety data from Avandia trials which demonstrated an estimate of excess risk of ischemic cardiovascular events and other data about the safety of Avandia;

e. the Company's alleged marketing of bupropion (Wellbutrin) as a weight-loss aid spurred a Department of Justice investigation of the Company, including the recent indictment of a Company attorney for "ma[king] false statements and with[holding] documents she recognized as incriminating" from the government;

f. the Company's Paxil and Avandia problems largely contributed to a record charge adjusting earnings of $2.36 billion on or about July 15, 2010 and caused significant reputational damage to GSK;

g. the Company lacked adequate management controls to ensure that an effective quality system existed as required by FDA regulations;

h. because of the foregoing, the Company was at serious risk throughout the Class Period of civil suits and adverse governmental action, including possibly product seizure, injunctions and civil penalties;

i. and the Company's ADSs, as offered by the Fund, were unreasonably risky for retirement savings and a decrease in their value was a near certainty in light of the facts alleged by Plaintiffs.

JURISDICTION AND VENUE

4. Plaintiffs' claims arise under and pursuant to ERISA § 502, 29 U.S.C. § 1132.

5. This Court has jurisdiction over this action pursuant to ERISA § 502(e)(1), 29 U.S.C. § 1132(e)(1).

6. Venue is proper in this District pursuant to ERISA § 502(e)(2), 29 U.S.C. § 1132(e)(2), because this is a District where the Plans were administered, where breaches of fiduciary duty took place, where a GSK subsidiary handling investor relations is based (at 499 Park Avenue, New York, N.Y. 10022), where GSK's ADSs trade and/or where one or more Defendants reside or may be found.

THE PARTIES

7. Plaintiff Charles J. Gum is a resident of the State of Michigan. Plaintiff Gum was employed by GSK (or a subsidiary or division of GSK) for several years until July 2010, and maintained an investment in GSK ADSs in his individual account in the Plan during the Class Period. Plaintiff Gum is a Participant in the GSK Plan within the meaning of ERISA §§ 3(7) and 502(a), 29 U.S.C. §§ 1102(7) and 1132(a). Plaintiff Gum was appointed as an interim lead plaintiff pursuant to the Order Consolidating Related Actions and Appointing Interim Lead Plaintiffs and Interim Co-Lead Class Counsel, filed October 8, 2010 (the "Order") at ¶ 11.

8. Plaintiff Marilyn S. Hayes is a resident of the State of Tennessee. Plaintiff Hayes was employed by GSK (or a subsidiary or division of GSK) for several years from January 1989 until August 2010 and maintained an investment in GSK ADSs in her individual account in the Plan during the Class Period. Plaintiff Hayes is a Participant in the GSK Plan within the meaning of ERISA §§ 3(7) and 502(a), 29 U.S.C. §§ 1102(7) and 1132(a). Plaintiff Hayes was appointed as an interim lead plaintiff pursuant to ¶ 11 of the Order.

9. Defendant GSK is a developer and manufacturer of pharmaceuticals, including the drug Avandia (rosiglitazone), which was developed, manufactured and marketed as a treatment to control blood sugar in people with type 2 diabetes. GSK was formed through the December 27, 2000 merger (the "Merger") of GlaxoWellcome plc ("Glaxo") and SmithKline Beecham plc ("SmithKline") (formed through the 1988 merger of SmithKline Beckman

Corporation and Beecham plc). GSK's ADSs trade in an efficient market on the New York Stock Exchange ("NYSE") under the symbol "GSK." GSK's ordinary shares trade in an efficient market on the London Stock Exchange ("LSE"). Its principal executive office is located at 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

10. Defendant GlaxoSmithKline LLC (the "LLC") is a private corporation which acts as the primary subsidiary of GSK operating within the United States. During the Class Period it was, at relevant times, *inter alia*, registered with the States of Delaware and/or Pennsylvania. Its principal place of business is One Franklin Plaza (FP 2220), Philadelphia, PA 19101. The Vanguard Fiduciary Trust Company Target Retirement Trust II Investment Authorization and Adoption Agreement (the "Vanguard Agreement"), signed with regard to the GSK Plan on February 22, 2010, identifies the GSK Plan's Sponsoring Employer as the LLC.

11. The Form 11-K Annual Report filed with the Securities and Exchange Commission ("SEC") for the fiscal year ending December 31, 2009 (the "GSK Plan 2009 Form 11-K"), provides that the "[n]ame[s] of issuer of the securities held pursuant to the plan and address of its principal executive office" are both GSK and the LLC.

12. The GlaxoSmithKline Trust Investment Committee (the "TIC") "is responsible for carrying out investment policies associated with the Plan." GSK Investment Policy 2007 at 5; 2009 at 5. The TIC and members of the TIC were fiduciaries of the Plans within the meaning of ERISA § 3(21)(A) in that each member exercised discretionary authority with respect to the management, administration, and disposition of the Plans' assets. The GSK Board of Directors (the "GSK Board") and/or the LLC Board of Directors (the "LLC Board") (the GSK Board and LLC Board are collectively referred to herein as the "Boards"), directly or acting through one of its or their committees, appointed the TIC and its members, and the Boards, one

or both of them, and were thus responsible for properly appointing, monitoring and informing the TIC and its members so that they could properly discharge their fiduciary obligations under ERISA. *See* GSK Investment Policy 2007 at 3-5; GSK Investment Policy 2009 at 3-5; *see also* GSK Trust Investment Committee Charter (the "TIC Charter") at 1.

13. According to the TIC Charter, the TIC must hold at least four meetings per year "to review the business of the committee and prepare regular reports for the Board, or such committee of the Board as the Board may designate." *Id.* At its meetings, in addition to reviewing its own meeting minutes, the TIC reviews the Benefits Committee, as defined *infra*, meeting minutes. *See* TIC Meeting Minutes for September 9, 2005 through March 10, 2010. The TIC is also responsible for, *inter alia*, selecting and monitoring outside investment managers. TIC Charter at 1-2, 4, 7-8.

14. The GlaxoSmithKline Retirement Savings Plan Committee (the "Benefits Committee") was the named administrator of the Plans during the Class Period. The Benefits Committee and members of the Benefits Committee were fiduciaries of the Plans within the meaning of ERISA § 3(21)(A) in that each member exercised discretionary authority with respect to the management, administration, and disposition of the Plans' assets. The Boards, one or both of them, directly or acting through one of their committees, appointed the Benefits Committee and its members, and the Boards, one or both of them, were thus responsible for properly appointing, monitoring and informing the Benefits Committee and its members so that they could properly discharge their fiduciary obligations under ERISA. *See* GSK Investment Policy 2007 at 3-5; GSK Investment Policy 2009 at 3-5; *see also* GSK Benefits Committee Charter (the "Benefits Committee Charter") at 1. According to the GSK Investment Policy 2007 and GSK Investment Policy 2009, "the Benefits Committee which is responsible for

administering and interpreting the plan." GSK Investment Policy 2007 at 5; GSK Investment Policy 2009 at 5.

15. According to the Benefits Committee Charter, the Benefits Committee must hold at least four meetings per year "to review the business of the committee." Benefits Committee Charter at 1. At its meetings, in addition to reviewing its own meeting minutes, the Benefits Committee reviews the TIC meeting minutes. *See* Benefits Committee Meeting Minutes for June 2, 2005 through January 20, 2010. Further, *inter alia*, the Benefits Committee must "periodically prepare and deliver a written report to the Board or such committee of the Board as the Board may designate. Such report shall summarize the business of the Benefits Committee and shall evaluate the overall competitiveness of the benefits offered by the Company to its employees as compared to a select group of competitor companies." *Id.*

16. Does 1-50 were members of one or both of the Boards, the TIC and/or the Benefits Committee during times relevant to this Complaint. As members of the committee(s), Does 1-50 were fiduciaries with respect to the Plans and exercised discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Does 1-50 herein only to the extent, and while, the Does served as fiduciaries of the Plans. At this time, without further formal discovery, Plaintiffs do not have sufficient information to identify Does 1-50 by name.

17. Defendant Andrew Witty ("Witty") joined the GSK Board in January 2008, and became the Company's Chief Executive Officer ("CEO") on May 21, 2008. Witty originally joined Glaxo in 1985. Defendant Witty was a member of the GSK Board's Corporate Administration & Transactions Committee and Finance Committee. At times relevant to this Complaint, Defendant Witty was a fiduciary with respect to the Plans and exercised oversight

responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Witty herein only to the extent, and while, he served as a fiduciary of the Plans.

18. Defendant Jean-Pierre Garnier ("Garnier") became GSK's CEO and a member of the GSK Board after the Merger. Defendant Garnier held those positions until his retirement on May 21, 2009. Defendant Garnier joined SmithKline in 1990, and was a member of its board of directors and Chief Operating Officer from 1996 through the date of the Merger. Defendant Garnier has a master's degree in Pharmaceutical Science and a PhD in Pharmacology. At times relevant to this Complaint, Defendant Garnier was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Garnier herein only to the extent, and while, he served as a fiduciary of the Plans.

19. Defendant Julian Heslop ("Heslop") became GSK's Chief Financial Officer and a member of the GSK Board on April 1, 2005, having joined Glaxo in 1998. Defendant Heslop is a member of the GSK Board's Corporate Administration & Transactions Committee and Finance Committee. At all times relevant to this Complaint, Defendant Heslop was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Heslop herein only to the extent, and while, he served as a fiduciary of the Plans.

20. Defendant Moncef Slaoui ("Slaoui") became GSK's Chairman, Research & Development, and a member of the GSK Board on May 17, 2006. Defendant Slaoui holds a PhD in Molecular Biology and Immunology. Defendant Slaoui was a member of the GSK Board's

Corporate Administration & Transactions Committee and Finance Committee. At all times relevant to this Complaint, Defendant Slaoui was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Slaoui herein only to the extent, and while, he served as a fiduciary of the Plans.

21. Defendant Christopher Viehbacher ("Viehbacher") was a member of the GSK Board from January 31, 2008 through September 8, 2008. Defendant Viehbacher was also President, U.S. Pharmaceuticals from January 2003 through December 1, 2008, a division he joined in 1988. At times relevant to this Complaint, Defendant Viehbacher was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Viehbacher herein only to the extent, and while, he served as a fiduciary of the Plans.

22. Defendant Christopher Gent ("Gent") joined the GSK Board as Deputy Chairman on June 1, 2004 and became Chairman of the GSK Board on January 1, 2005. Defendant Gent was a member of the GSK Board's Corporate Administration & Transactions Committee, Finance Committee, and Remuneration Committee, and Chair of its Corporate Responsibility and Nominations Committees. At all times relevant to this Complaint, Defendant Gent was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Gent herein only to the extent, and while, he served as a fiduciary of the Plans.

23. Defendant Roy Anderson ("Anderson") joined the GSK Board on October 1, 2007. He previously held the position of Chief Scientific Adviser to the Ministry of Defense in the United Kingdom. Defendant Anderson was a member of the GSK Board's Audit Committee, Corporate Administration & Transactions Committee, and Finance Committee. At times relevant to this Complaint, Defendant Anderson was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Anderson herein only to the extent, and while, he served as a fiduciary of the Plans.

24. Defendant Stephanie Burns ("Burns") joined the GSK Board on February, 12, 2007. Defendant Burns holds a PhD in Organic Chemistry. Defendant Burns was a member of the GSK Board's Corporate Administration & Transactions Committee, Corporate Responsibility Committee, and Finance Committee. At all times relevant to this Complaint, Defendant Burns was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Burns herein only to the extent, and while, she served as a fiduciary of the Plans.

25. Defendant Lawrence Culp ("Culp") joined the GSK Board on July 1, 2003. Defendant Culp was a member of the GSK Board's Corporate Administration & Transactions Committee, Finance Committee, Nominations Committee, and Remuneration Committee. At all times relevant to this Complaint, Defendant Culp was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Culp herein only to the extent, and while, he served as a fiduciary of the Plans.

26. Defendant Crispin Davis ("Davis") joined the GSK Board on July 1, 2003. Defendant Davis was a member of the GSK Board's Corporate Administration & Transactions Committee, Finance Committee, and Nominations Committee, and Chair of the Remuneration Committee. At all times relevant to this Complaint, Defendant Davis was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Davis herein only to the extent, and while, he served as a fiduciary of the Plans.

27. Defendant Deryck Maughan ("Maughan") joined the GSK Board on June 1, 2004. Defendant Maughan was a member of the GSK Board's Audit Committee, Corporate Administration & Transactions Committee, Finance Committee, and Nominations Committee. At all times relevant to this Complaint, Defendant Maughan was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Maughan herein only to the extent, and while, he served as a fiduciary of the Plans.

28. Defendant James Murdoch ("Murdoch") joined the GSK Board on May 20, 2009. Defendant Murdoch was a member of the GSK Board's Corporate Administration & Transactions Committee, Finance Committee, Corporate Responsibility Committee, and Remuneration Committee. At times relevant to this Complaint, Defendant Murdoch was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Murdoch herein only to the extent, and while, he served as a fiduciary of the Plans.

29. Defendant Daniel Podolsky ("Podolsky") joined the GSK Board on July 1, 2006. Defendant Podolsky was a member of the GSK Board's Audit Committee, Corporate Administration & Transactions Committee, Corporate Responsibility Committee, and Finance Committee. He is a licensed medical doctor practicing with Massachusetts General Hospital and Harvard Medical School. At all times relevant to this Complaint, Defendant Podolsky was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Podolsky herein only to the extent, and while, he served as a fiduciary of the Plans.

30. Defendant Ian Prosser ("Prosser") joined the SmithKline board of directors on May 23, 2000, and became a member of the GSK Board after the Merger. Defendant Prosser retired from the GSK Board on May 20, 2009. At times relevant to this Complaint, Defendant Prosser was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Prosser herein only to the extent, and while, he served as a fiduciary of the Plans.

31. Defendant Ronaldo Schmitz ("Schmitz") joined the Glaxo board of directors on January 23, 2000, and became a member of the GSK Board after the Merger. Defendant Schmitz retired from the GSK Board on May 20, 2009. At times relevant to this Complaint, Defendant Schmitz was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Schmitz herein only to the extent, and while, he served as a fiduciary of the Plans.

32. Defendant Tom de Swaan ("Swaan") became a member of the GSK Board on January 1, 2006, and was the Chairman of the Company's Audit Committee. Defendant Swaan was also a member of the GSK Board's Corporate Administration & Transactions Committee, Finance Committee, Corporate Responsibility Committee, and Remuneration Committee. At all times relevant to this Complaint, Defendant Swaan was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Swaan herein only to the extent, and while, he served as a fiduciary of the Plans.

33. Defendant Robert Wilson ("Wilson") became a member of the GSK Board on November 2, 2003. Defendant Wilson was a member of the GSK Board's Audit Committee, Corporate Administration & Transactions Committee, Finance Committee, and Nominations Committee. At all times relevant to this Complaint, Defendant Wilson was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Wilson herein only to the extent, and while, he served as a fiduciary of the Plans.

34. Defendants Witty, Garnier, Heslop, Slaoui, Viehbacher, Gent, Anderson, Burns, Culp, Davis, Maughan, Murdoch, Podolsky, Prosser, Schmitz, Swaan, and Wilson and certain Does, are collectively hereinafter referred to as the "Director Defendants."

35. As specifically delineated in the GSK Plan Investment Policy 2007 at 3, GSK Investment Policy 2009 at 3 and outlined *infra*, the Director Defendants are each fiduciaries of Plan due to their status as members of one or each of the Boards. In addition, the members of

one and/or both Boards "[a]ppoints" the GSK TIC, "which is responsible for carrying out investment policies associated with the Plan." *Id.*

36. Defendant M. Judith Lynch ("Lynch"), at all times relevant to this Complaint, was GSK's Senior Vice President-Benefits. The GSK Investment Policy 2007 and GSK Investment Policy 2009, which state that members of the TIC are fiduciaries of the Plans, specifically identifies Defendant Lynch as a member of the TIC. The GSK Investment Policy 2007 and GSK Investment Policy 2009 also identify Defendant Lynch as a member of the Benefits Committee. On June 27, 2008, Defendant Lynch signed, on behalf of the Puerto Rico Plan, the Puerto Rico Plan's 11-K Annual Report, filed with the SEC, for the Puerto Rico Plan's year ended December 31, 2007 (the "Puerto Rico Plan 2007 11-K"). At all times relevant to this Complaint, Defendant Lynch was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans, and with respect to the respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Lynch herein only to the extent, and while, she served as a fiduciary of the Plans.

37. Defendant Michelle Killian ("Killian") is, and at all times relevant to this Complaint was, GSK's Vice President-U.S. Benefits. The GSK Investment Policy 2007 and GSK Investment Policy 2009, which state that members of the TIC are fiduciaries of the Plans, specifically identifies Defendant Killian as a member of the TIC. The GSK Investment Policy 2007 and GSK Investment Policy 2009 also identify Defendant Killian as a Chair of the Benefits Committee. On June 27, 2007, Defendant Killian signed, on behalf of the GSK Plan, the GSK Plan's 11-K Annual Report, filed with the SEC, for the GSK Plan's year ended December 31, 2006 (the "GSK Plan 2006 11-K"). On June 21, 2009, Defendant Killian signed, on behalf of

the GSK Plan, the GSK Plan's 11-K Annual Report for the GSK Plan for the 2009 fiscal year (the "GSK Plan 2009 11-K"). On June 23, 2008, Defendant Killian signed, on behalf of the Puerto Rico Plan, the Puerto Rico Plan 2007 11-K. Defendant Killian also signed, as plan administrator and employer/plan sponsor/DFE, the Company's Annual Return/Report of Employee Benefit Plan ("Return/Report"), filed with the Department of Labor ("DOL") on Form 5500 for the year ended December 31, 2007 ("2007 Form 5500") and the Return/Report filed with the DOL on Form 5500 for the year ended December 31, 2008 ("2008 Form 5500"). At all times relevant to this Complaint, Defendant Killian was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans, and with respect to the respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Killian herein only to the extent, and while, she served as a fiduciary of the Plans.

38. Defendant David Downes ("Downes"), a non-employee of GSK, was specifically identified by the GSK Investment Policy 2007 and GSK Investment Policy 2009, which state that members of the TIC are fiduciaries of the Plans, as GSK TIC Chairman. At all times relevant to this Complaint, Defendant Downes was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Downes herein only to the extent, and while, he served as a fiduciary of the Plans.

39. Defendant Roger Emerson ("Emerson") at all times relevant to this Complaint was GSK's Senior Vice President-Tax Treasury. The GSK Investment Policy 2007, which states that members of the TIC are fiduciaries of the Plans, specifically identifies Defendant Emerson as a member of the TIC. At times relevant to this Complaint, Defendant Emerson was a

fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Emerson herein only to the extent, and while, he served as a fiduciary of the Plans.

40. Defendant Michael Corrigan ("Corrigan"), at all times relevant to this Complaint, was GSK's Senior Vice President-Finance US. The GSK Investment Policy 2007 and GSK Investment Policy 2009, which state that members of the TIC are fiduciaries of the Plans, specifically identifies Defendant Corrigan as a member of the TIC. At all times relevant to this Complaint, Defendant Corrigan was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Corrigan herein only to the extent, and while, he served as a fiduciary of the Plans.

41. Defendant Eleanor Barger ("Barger"), at all times relevant to this Complaint, was GSK's Senior Vice President World Wide Consumer Health. The GSK Investment Policy 2007 and GSK Investment Policy 2009, which state that members of the TIC are fiduciaries of the Plans, specifically identifies Defendant Barger as a member of the TIC. At all times relevant to this Complaint, Defendant Barger was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Barger herein only to the extent, and while, she served as a fiduciary of the Plans.

42. Defendant Eileen C. Leahy ("Leahy"), at all times relevant to this Complaint, was GSK's Assistant Treasuer-Benefit Finance. The GSK Investment Policy 2007 and GSK Investment Policy 2009, which state that members of the TIC are fiduciaries of the Plans,

specifically identify Defendant Leahy as a member of the TIC. The GSK Investment Policy 2007 and GSK Investment Policy 2009 also identify Defendant Leahy as a member of the Benefits Committee. Defendant Leahy also signed the Vanguard Agreement, as the Authorized Representative of the TIC, on February 22, 2010. At all times relevant to this Complaint, Defendant Leahy was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans, and with respect to the respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Leahy herein only to the extent, and while, she served as a fiduciary of the Plans.

43. Defendant Michael J. Smithwick ("Smithwick"), at times relevant to this Complaint, was GSK's Manager-Benefit Finance. The GSK Investment Policy 2007, which states that members of the TIC are fiduciaries of the Plans, specifically identifies Defendant Smithwick as a member and Secretary of the TIC. At times relevant to this Complaint, Defendant Smithwick was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Smithwick herein only to the extent, and while, he served as a fiduciary of the Plans.

44. Defendant Sarah-Jane Chilver-Stainer ("Stainer") was identified as a member of the TIC in its Meeting Minutes dated September 26, 2008, November 21, 2008, February 24, 2009, May 19, 2009, September 23, 2009, December 9, 2009, March 10, 2009, and June 9, 2010. At times relevant to this Complaint, Defendant Stainer was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to

carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Stainer herein only to the extent, and while, she served as a fiduciary of the Plans.

45. Defendant Moria Beckwith ("Beckwith") was identified as a new member of the TIC in its Meeting Minutes dated June 9, 2010. At times relevant to this Complaint, Defendant Beckwith was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Beckwith herein only to the extent, and while, she served as a fiduciary of the Plans.

46. Defendant Philip Driver ("Driver") was identified as a new member of the TIC in its Meeting Minutes dated June 9, 2010. At times relevant to this Complaint, Defendant Driver was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Driver herein only to the extent, and while, he served as a fiduciary of the Plans.

47. Defendant Charles Kelly ("Kelly") was identified as a new member of the TIC in its Meeting Minutes dated June 9, 2010. At times relevant to this Complaint, Defendant Kelly was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Kelly herein only to the extent, and while, he served as a fiduciary of the Plans.

48. Defendant William Shulby ("Shulby") was identified as a new member of the TIC in its Meeting Minutes dated June 9, 2010. At times relevant to this Complaint, Defendant Shulby was a fiduciary with respect to the Plans and exercised oversight responsibility and

discretionary authority and/or control with respect to carrying out the investment policies associated with the Plans. Liability is asserted against Defendant Shulby herein only to the extent, and while, he served as a fiduciary of the Plans.

49. Defendants Lynch, Killian, Downes, Emerson, Corrigan, Barger, Leahy, Smithwick, Stainer, Beckwith, Driver, Kelly and Shulby are collectively hereinafter referred to as the "TIC Defendants."

50. Defendant Stephen Burr ("Burr"), at all times relevant to this Complaint, was GSK's Senior Vice President, Human Resources, US Pharmaceuticals. The GSK Investment Policy 2007 and GSK Investment Policy 2009 specifically identify Defendant Burr as a member of the Benefits Committee. At all times relevant to this Complaint, Defendant Burr was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Burr herein only to the extent, and while, he served as a fiduciary of the Plans.

51. Defendant Bill Mills ("Mills"), at times relevant to this Complaint, was GSK's Senior Vice President, Human Resources NA, Consumer Healthcare. The GSK Investment Policy 2007 specifically identifies Defendant Mills as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Mills was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Mills herein only to the extent, and while, he served as a fiduciary of the Plans.

52. Defendant Nancy Marsh ("Marsh"), at all times relevant to this Complaint, was GSK's Senior Vice President, Human Resources, Research & Development. The GSK

Investment Policy 2007 and GSK Investment Policy 2009 specifically identify Defendant Marsh as a member of the Benefits Committee. At all times relevant to this Complaint, Defendant Marsh was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Marsh herein only to the extent, and while, she served as a fiduciary of the Plans.

53. Defendant David J. Jones ("Jones"), at times relevant to this Complaint, was GSK's Senior Vice President, Human Resources, GMS. The GSK Investment Policy 2007 specifically identifies Defendant Jones as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Jones was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Jones herein only to the extent, and while, he served as a fiduciary of the Plans.

54. Defendant Fabrice Enderlin ("Enderlin"), at times relevant to this Complaint, was GSK's Vice President, Human Resources, HR Management, Rixensart. The GSK Investment Policy 2007 specifically identifies Defendant Enderlin as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Enderlin was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Enderlin herein only to the extent, and while, she served as a fiduciary of the Plans.

55. Defendant Cathryn Campbell ("Campbell"), at times relevant to this Complaint, was GSK's Vice President, Human Resources, IT. The GSK Investment Policy 2007 specifically identifies Defendant Campbell as a member of the Benefits Committee. At times

relevant to this Complaint, Defendant Campbell was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Campbell herein only to the extent, and while, she served as a fiduciary of the Plans.

56. Defendant Jan Fenton ("Fenton"), at times relevant to this Complaint, was GSK's Vice President, Corporate Human Resources Operations. The GSK Investment Policy 2007 specifically identifies Defendant Fenton as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Fenton was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Fenton herein only to the extent, and while, she served as a fiduciary of the Plans.

57. Defendant Ann Kuhnen ("Kuhnen"), at all times relevant to this Complaint, was GSK's Vice President, Employee Health Management, Shared Services US. The GSK Investment Policy 2007 and GSK Investment Policy 2009 specifically identify Defendant Kuhnen as a member of the Benefits Committee. At all times relevant to this Complaint, Defendant Kuhnen was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Kuhnen herein only to the extent, and while, she served as a fiduciary of the Plans.

58. Defendant Stephen Ethridge ("Ethridge"), at times relevant to this Complaint, was GSK's Vice President, Human Resources, Consumer HC Supply. The GSK Investment Policy 2007 specifically identifies Defendant Ethridge as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Ethridge was a fiduciary with respect to the Plans

and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Ethridge herein only to the extent, and while, he served as a fiduciary of the Plans.

59. Defendant William Mosher ("Mosher"), at all times relevant to this Complaint, was Vice President, Legal Operations, Information Technology. The GSK Investment Policy 2007 and GSK Investment Policy 2009 specifically identify Defendant Mosher as a member of and Counsel to the Benefits Committee. At all times relevant to this Complaint, Defendant Mosher was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Mosher herein only to the extent, and while, he served as a fiduciary of the Plans. According to the TIC Meeting Minutes dated June 9, 2010, for the TIC meeting held on March 10, 2010 (the "March 10, 2010 TIC Minutes"), Defendant Mosher also presented the TIC and its members with an overview of the responsibilities of a fiduciary as it relates to the TIC. *See* March 10, 2010 TIC Minutes at 1. Further, Defendant Mosher assisted the TIC members in reviewing the TIC Charter and providing revisions to it.

60. Defendant Ian Cardwell ("Cardwell"), at times relevant to this Complaint, was Vice President, Human Resources, GMS. The GSK Investment Policy 2009 specifically identifies Defendant Cardwell as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Cardwell was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Cardwell herein only to the extent, and while, he served as a fiduciary of the Plans.

61. Defendant Diana Conrad ("Conrad") at times herein relevant was Vice President, Human Resources, Consumer Healthcare, NA. The GSK Investment Policy 2009 specifically identifies Defendant Conrad as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Conrad was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Conrad herein only to the extent, and while, she served as a fiduciary of the Plans.

62. Defendant Beverly E. Morgan ("Morgan"), at times relevant to this Complaint, was Vice President, Human Resources, IT. The GSK Investment Policy 2009 specifically identifies Defendant Morgan as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Morgan was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Morgan herein only to the extent, and while, she served as a fiduciary of the Plans.

63. Defendant Stuart Hebpurn ("Hebpurn"), at times relevant to this Complaint, was Vice President, Corporate Human Resources Operations. The GSK Investment Policy 2009 specifically identifies Defendant Hebpurn as a member of the Benefits Committee. At times relevant to this Complaint, Defendant Hebpurn was a fiduciary with respect to the Plans and exercised oversight responsibility and discretionary authority and/or control with respect to the management and administration of the Plans. Liability is asserted against Defendant Hebpurn herein only to the extent, and while, he served as a fiduciary of the Plans.

64. Defendants Lynch, Killian, Burr, Mills, Marsh, Jones, Enderlin, Campbell, Fenton, Kuhnen, Ethridge, Leahy, Mosher, Cardwell, Conrad, Morgan and Helpburn are collectively hereinafter referred to as the "Benefits Committee Defendants."

65. Defendants Does 1-50, the Director Defendants, the TIC Defendants and the Benefits Committee Defendants are collectively hereinafter referred to as the "Individual Defendants."

66. All of the Individual Defendants were *de facto* fiduciaries of the Plans as a result of their discretionary authority or control over the Plans under the very broad definition of "fiduciary" set forth in ERISA at § 3(21)(A), 29 U.S.C. § 1002(21)(A). A person or entity is a fiduciary even if the Plans do not name him as such or by its terms assign fiduciary duties to him where, by his conduct, he engages in fiduciary activities. Those who have discretion over management of the Plans or the Plans' assets are fiduciaries regardless of the labels or duties assigned to them by the language of the Plans. Moreover, in order to fulfill the express remedial purpose of ERISA, the definition of "fiduciary" is construed broadly.

67. The GSK Retirement Savings Plan Summary Plan Description and Prospectus dated July 1, 2007 (the "GSK SPD"), in a subsection entitled "Prudent Actions by Plan Fiduciaries" states, in part, that:

> In addition to creating rights for participants in the Plan, ERISA imposed duties upon the people who are responsible for the operation of the Plan. The people who administer the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other participants and beneficiaries.

GSK SPD at 40.

68. According to the governing GSK Plan document as amended and restated effective July 1, 2001, as amended through November 26, 2002 (the "2001 Plan Document"), the "Company shall be Administrator of the Plan for purposes of ERISA." 2001 Plan Document at

42, Art. 9.1. The term "Company" is defined as "SmithKline Beecham Corporation d/b/a GlaxoSmithKline, a Pennsylvania corporation and successor by merger of Glaxo Wellcome Inc. and SmithKline Beecham Corporation." *Id*. at 4. The 2001 Plan Document also identifies the "Company" as the GSK Plan's "Named Fiduciary." *Id.* at 42, Art. 9.2. However, according to the document:

> . . . The Company may, however, by or pursuant to a resolution of its Board of Directors, delegate to any person or entity any of its powers or duties under the Plan. To the extent of any such delegation, the delegate shall become the named fiduciary responsible for administration of the Plan (if the delegate is the fiduciary by reason of the delegation), and assigning any of its responsibilities to specific persons who are all directors, officers or employees of the Company shall not constitute delegation of the Company's responsibility but rather shall be treated as a the manner in which the Company has determined internally to discharge such responsibility.

Id.

69. The 2001 Plan Document further defines the term "Committee" to "mean[] the individuals appointed by the Company to serve on the GlaxoSmithKline Benefits Committee to supervise the administration of the Plan, as provided by Article 9." *Id*. at 4. Article 9, also cited *supra*, states, in part, that "[t]he Committee shall be the named fiduciary which shall control and manage the operation of the Plan and shall administer the Plan." *Id*. at 42, Art. 9.3.

70. In addition, the GSK Plan Investment Policy 2007 also includes the TIC as fiduciaries of the GSK Plan. Specifically, the GSK Investment Policy 2007 states, in part, that ERISA defines a plan fiduciary as one who:

> (i) Exercises any authority or control concerning management and the disposition of plan assets;
>
> (ii) Renders investment advice with respect to plan assets (or has any authority or responsibility to do so; or

> (iii) Exercises any discretionary authority or responsibility in the administration of the plan.
>
> SmithKline Beecham Corporation. (the Smith Kline Beecham Corporation. Board of Directors), Trustees, members of the [GSK] Trust Investment Committee, and investment managers (advisors) are fiduciaries of the GSK [Plan]. Plan accountants and consultants are not fiduciaries when performing their usual professional functions; however, if the nature of their professional functions falls within the standards cited above, they become plan fiduciaries."

Id. at 3.

71. The governing GSK Plan document, *inter alia*, as amended and restated effective January 1, 2009 (the "2009 Plan Document"), revises the defined term "Company" from the definition provided in the 2001 Plan Document. According to the 2009 Plan Document, the term "'Company' means GlaxoSmithKline LLC, a Delaware limited liability company."

72. The breaches of fiduciary duty committed by the Individual Defendants, as alleged herein, were committed by the Individual Defendants in the course of their employment by the Company (in the case of Defendants Does 1-50, Witty, Garnier, Heslop, Slaoui, Viehbacher Killian and Lynch) and in the course of their compensated affiliation with and service to the Company and the Plans (in the case of the Director Defendants). Accordingly, GSK is liable, under the doctrine of *respondeat superior*, for the breaches of fiduciary duty alleged herein. Alternatively, GSK, and/or the LLC which was the Named Fiduciary of the Plans, is liable as a co-fiduciary because it had knowledge of the Individual Defendants' breaches of their fiduciary duties and did not make reasonable efforts to remedy those breaches.

CLASS ACTION ALLEGATIONS

73. Plaintiffs bring this action on their own behalf and as a class action pursuant to Rules 23(a), (b)(1)(B), and/or (b)(3) of the Federal Rules of Civil Procedure, on behalf of a class consisting of all current and former Participants in the Plans for whose individual accounts the

Plans held shares of GSK ADSs (including in the form of units of the GSK Stock Fund) at any time from May 8, 2007 through November 9, 2010 (the "Class").

74. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are, at minimum, thousands of members of the Class. According to the 2007 Form 5500, there were 33,292 participants in the GSK Plan as of December 31, 2007. According to the 2008 Form 5500, there were 31,587 participants in the GSK Plan as of December 31, 2008.

75. Common questions of law and fact exist as to all members of the Class which predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

a. Whether Defendants were fiduciaries;

b. Whether Defendants breached their fiduciary duties;

c. Whether the Plans and the Participants were injured by such breaches; and

d. Whether the Class is entitled to damages and injunctive relief.

76. Plaintiffs' claims are typical of the claims of the other members of the Class, as Plaintiffs and all members of the Class sustained injury arising out of Defendants' wrongful conduct in breaching their fiduciary duties and violating ERISA as complained of herein.

77. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained able counsel with extensive experience in class action ERISA litigation. The interests of Plaintiffs are coincident with and not antagonistic to the interests of the other Class members.

78. Prosecution of separate actions by members of the Class would create a risk of inconsistent adjudications with respect to individual members of the Class which would establish incompatible standards of conduct for Defendants, or adjudications with respect to individual members of the Class would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

79. Questions of law and fact which are common to the members of the Class will predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this Complaint, taking into account:

a. the interest of members of the Class in individually controlling the prosecution or defense of separate actions;

b. the extent and nature of any litigation concerning the controversy already commenced by or against members of the Class;

c. the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

d. the difficulties likely to be encountered in the management of a class action.

80. Moreover, because the damages suffered by many of the Participants will be relatively small, the expense and burden of individually litigating their rights would make it impossible to individually redress the wrongs alleged herein.

81. The claims herein are under ERISA and related principles of federal common law cannot be asserted by plaintiffs in derivative actions against the Company or in class actions under securities law.

DESCRIPTION OF THE PLAN

82. "The objective of the GSK Retirement Savings Plan is to encourage and help [the Participants] save regularly toward retirement." GSK SPD at 3; *see also id.* at 17 ("the main objective of the Plan is to provide income for your retirement"); GSK Plan Investment Policy 2007 ("The Purpose of the [GSK Plan] is to encourage employee savings through a systematic means to provide additional security for retirement.") The SPD identifies the "Plan Sponsor" as SmithKline Beecham Corporation d/b/a GlaxoSmithKline.

83. According to the GSK Plan's "Total Reward[:] dimensions" newsletter (the "Dimensions Newsletter"), dated November 2008, edited by GSK employees from various departments in the United States and United Kingdom, as outlined *infra*, and sent by Defendants during the Class Period to, *inter alia*, members of the purported Class who were then United States employees, the Plans are "a long-term investment."

84. At all times relevant to this Complaint, the Plans were employee benefit plans within the meaning of ERISA §§ 3(3) and 3(2)(A), 29 U.S.C. §§ 1002(3) and 1002(2)(A). In a subsection entitled "Application of ERISA to the Plan," the GSK SPD states:

> The Retirement Savings Plan is a "defined contribution plan,' as described in Sections 3(34) of the Employee Retirement Income Security Act of 1974, as amended (ERISA). As such, the Plan is subject to the applicable provisions set forth in Part 1 (Reporting and Disclosure), Part 2 (Participation and Vesting), Part 4 (Fiduciary Responsibility) and Part 5 (Administration and Enforcement) of Subtitle B of Title I of ERISA which relate to employee pension benefit plans.

GSK SPD at 40.

85. At times prior to the Class Period, the 2001 Plan Document, which at all times relevant herein, has been one of the documents governing the GSK Plan, provides, in part, the history of the GSK Plan, which includes:

- Prior to April 1, 1990, the GSK Plan was known as the SmithKline Beecham Savings and Investment Plan;
- Effective April 1, 1990, the GSK Plan became known as the SmithKline Beecham Retirement Savings Plan (the "SK Plan");
- Glaxo and, after March 31, 2001, SmithKline Beecham Corporation, sponsor the Glaxo Wellcome 401(k) Plan (the "Glaxo Plan"), formerly known as the Glaxo Thrift Plan;
- The Glaxo Plan was amended and restated effective June 14, 1999; and
- As a result of the Merger, Glaxo and SmithKline merged the GSK Plan and the Glaxo Plan, and the merged plan became known as the GSK Plan effective July 1, 2001.

86. According to the GSK Plan's 2006 11-K, the GSK Plan's 2008 11-K, the GSK Plan's 2009 11-K, and the Puerto Rico Plan's 2007 11-K:

> The Plan was established to encourage and assist Company employees to save regularly for retirement. The Plan is subject to the provisions of the Employee Retirement Income Security Act of 1974 (ERISA).

This statement was reiterated in the GSK Plan's Financial Statements as of the years ended December 31, 2009 and 2008, and Supplemental Schedule as of December 31, 2009 (the "GSK Plan 2008/2009 Statements"), submitted to the SEC on or about June 15, 2010.

87. As noted *supra*, at all times relevant to this Complaint, the Plans were "defined contribution" or "individual account" plans within the meaning of ERISA § 3(34), 29 U.S.C.

§ 1002(34), in that the Plans provided for individual accounts for each Participant and for benefits based solely upon the amount contributed to the Participant's account, and any income, expenses, gains and losses, and any forfeitures of accounts of other Participants which could be allocated to such Participant's accounts. In fact, both the GSK Plan 2006 11-K and Puerto Rico Plan 2007 11-K specifically state that the Plans are defined contribution plans. *See also* GSK SPD at 40 (the "Plan is a 'defined contribution plan,' as described in Sections 3(34) of [ERISA]").

88. According to the GSK Plan 2006 11-K, "eligible employees with one hour of credited service may voluntarily elect to contribute pre-tax contributions ranging from 1% to 50% of the eligible compensation." Further, the "Company contributes matching contributions to participating employees with one year of service in an amount equal to the employee's pre-tax contribution not in excess of 4% of the employee's eligible compensation." This information regarding the match is reiterated in the GSK SPD. *See, e.g.*, GSK SPD at 1, 3-5.

89. According to the Puerto Rico Plan 2007 11-K, "participants may contribute up to 10% of after-tax annual compensation." Further, the "Company contributes matching contributions to participating employees with one year of service in an amount equal to 100% of the employee's pre-tax contribution not in excess of 4% of the employee's eligible compensation."

90. At all times relevant to this Complaint, Participants directed the Plans to purchase investments from among the investment options available under the Plans and allocated them to their individual accounts.

91. At all times relevant to this Complaint, the Plans provided a number of different investment options, including GSK ADSs through the GSK Stock Fund. Hundreds of millions of

dollars of the Plans' assets were invested in the Fund during the Class Period despite the Fund's imprudence for the Plans' Participants retirement savings, and the Plans suffered significant losses as a result thereof.

92. According to the GSK Plan 2006 11-K, "[t]he GlaxoSmithKline Stock Fund invests in American Depository Shares ("ADSs") each of which represents two ordinary shares of GlaxoSmithKline Plc." *See also* GSK SPD at 14.

93. According to the GSK Plan 2006 11-K, as of December 31, 2006, the GSK Plan held $901,453,350 in the Fund, and as of December 31, 2005, the GSK Plan held $919,001,626 in the Fund. According to the GSK Plan 2008/2009 Statements, as of December 31, 2008, the GSK Plan held $550,537,718 in the Fund, and as of December 31, 2009, the GSK Plan held $633,738,509 in the Fund.

94. According to the Puerto Rico Plan 2007 11-K, as of December 31, 2006 the Puerto Rico Plan held $19,407,709 in the Fund. As of December 31, 2006, the GSK Plan held $21,879,888 in the Fund.

95. According to the Trust Agreement between SmithKline and State Street Bank Trust Company dated June 27, 2001 (the "Trust Agreement") at § 3.2:

> Company Managed Stock Investment Accounts. If, and to the extent specifically authorized by the Plans, the Company may direct the Trustee to establish one or more Investment Funds substantially all of the assets of which shall be invested in securities which constitute "qualifying employer securities" or "qualifying employer real property" within the meaning of Section 407 of ERISA. It shall be the duty of the Company to determine that such investment is not prohibited by Sections 406 or 407 ERISA. In addition, during any time when there is no Investment Manager with respect to a Company Managed Stock Account (such as before an investment management agreement takes effect or after it terminates), the Administrator shall direct the investment and reinvestment of such Company Managed Stock Account

96. According to the Trust Agreement at § 3.3:

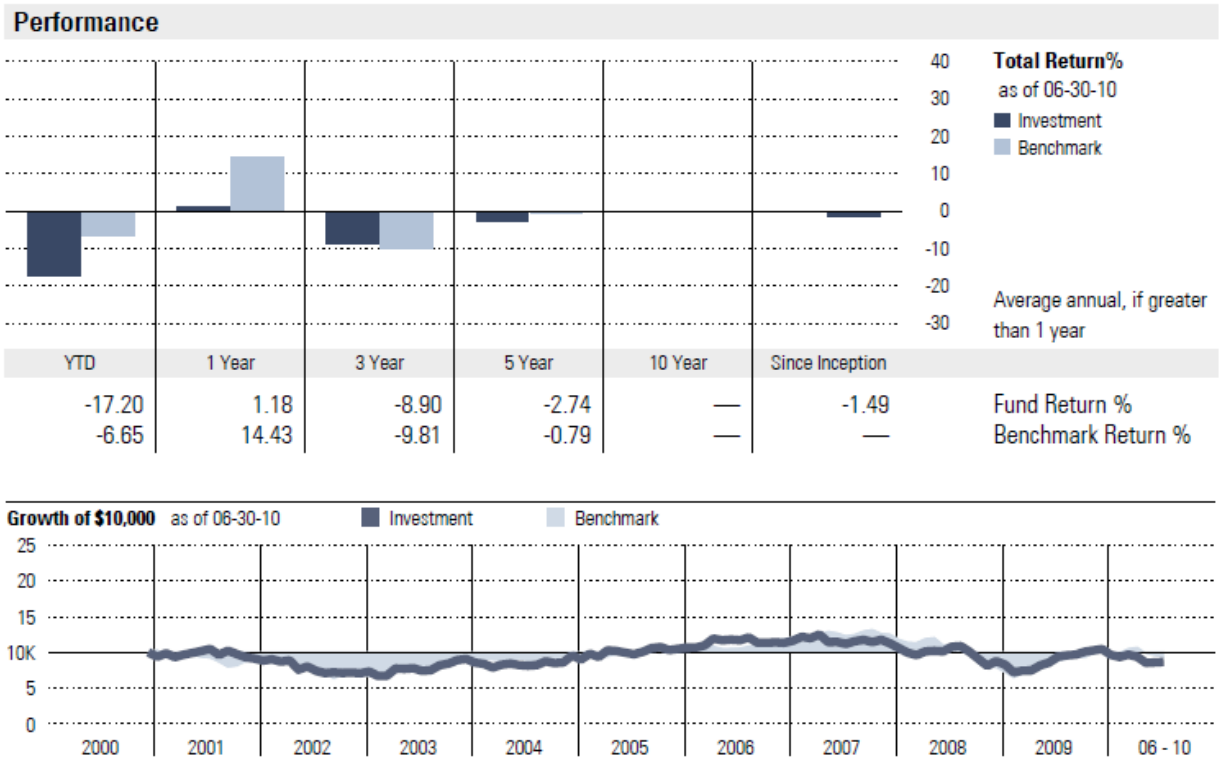
> Company Managed Investment Accounts. The Trustee shall, if so directed in writing by the Company, segregate all or a portion of the Trust Fund held by it intone or more separate investment accounts to be known as Company Managed Investment Accounts. The Company, by written notice to the Trustee, may at any time relinquish its powers under this Section 3.4 and direct that a Company Managed Investment Account shall no longer be maintained. Whenever the Administrator or named fiduciary is directing the investment and reinvestment of an Investment Account or a Company Managed Investment Account, the Administrator or named fiduciary shall have the powers and duties which an Investment Manager would have under this Trust Agreement if an Investment Manager were then serving and the Trustee shall be protected to the same extent as it would be protected under this Trust Agreement as to directions or the absence of directions of an Investment Manager.

97. According to the Benefits Committee Meeting Minutes for June 2, 2005 at 1-2:

> A presentation was made to the Committee that discussed employee investment in the GSK Stock Fund held in the Retirement Savings Plan (RSP). There is a new type of class action lawsuit being filed against plan fiduciaries by plan participants when a company's stock has a significant drop in stock price. The Committee was advised that GSK stock represents 24% of the RSP assets and that ***employees may not understand the investment risk associated with holding a single company stock. The Committee was advised that the Trust Investment Committee (TIC) is interested in establishing limits on employee investment in GSK stock in the RSP.*** The Committee was asked to give its opinion on the TIC's interest. The Committee recommends keeping GSK stock as an investment feature in the RSP and not impose limits on the amount of stock that employees can own. The Committee requests that communications be developed that educate and alert employees to the risks associated with owning single stock investments.

(Emphasis added).

98. A GSK Plan Participant communication discussing the Fund, which was released on or about June 30, 2010, reported that the Fund had significantly underperformed its benchmark, the S&P 500 Index, in 2010 through June 30, 2010 and for the one year period ended June 30, 2010. The communication included a graph showing:



99. Consistent with and further to the June 30, 2010 Plan communication, the value of GSK ADSs has declined precipitously during the Class Period.

ADMINISTRATION OF THE PLANS

100. Defendants, as fiduciaries of the Plans, were required by ERISA to furnish certain information to Participants. For example, ERISA § 101, 29 U.S.C. § 1021, requires the Plans' Administrator to furnish Summary Plan Descriptions ("SPD") to Participants. ERISA § 102, 29 U.S.C. § 1022, provides that an SPD must apprise Participants of their rights and obligations under the Plans.

101. At all times relevant to this Complaint, Defendants had the discretion to establish and change the investment alternatives among which Participants could direct the investment of the Plans' assets allocated to their accounts.

102. At all times relevant to this Complaint, Defendants had a duty to review the Plans' investment policies and the selection and the performance of investment alternatives offered under the Plans. There was no requirement that any assets of the Plans be invested in Company stock or that Company stock be continued as an investment alternative.

103. At all times relevant to this Complaint, Defendants had a duty to obtain from the Company information necessary for the proper administration of the Plans.

104. At all times relevant to this Complaint, Defendants were fiduciaries of the Plans, as defined by ERISA § 3(21)(A), 29 U.S.C. § 1002(21)(A), because they exercised discretionary authority or control respecting management of the Plans or exercised discretionary authority or control respecting management or disposition of assets and had discretionary authority or responsibility in the administration of the Plans.

105. Each Defendant is liable for the breaches of fiduciary duty of the other Defendants under ERISA § 405, 29 U.S.C. § 1105.

BREACHES OF FIDUCIARY DUTY

106. As required by ERISA, Defendants issued one or more SPDs, each of which either referred to or incorporated by reference the documents filed by GSK with the SEC under the federal securities laws. These filings, however, contained numerous material misrepresentations and omitted to state material facts, which were necessary to make the statements which were made not misleading.

107. GSK's SEC filings during the Class Period, as incorporated into the SPDs, negligently omitted to disclose to the Participants important information concerning the Company's business, operations, regulatory compliance and prospects.

108. According to the GSK SPD, "[i]n addition to creating rights for participants in the Plan, ERISA imposes duties upon the people who are responsible for the operation of the Plan.

The people who administer the Plan, called 'fiduciaries' of the Plan, have a duty to do so prudently and in the interest of you and other participants and beneficiaries." GSK SPD at 40.

109. Among other things, the SEC filings and SPDs failed to disclose that Avandia, GSK's popular diabetes drug, caused an increase risk of heart attacks and strokes in patients taking the drug, as outlined in the Nissen Study (defined *infra*). [1] Further, *inter alia*, Defendants also negligently omitted to Participants important information regarding the Company's Cidra, Puerto Rico plant; specifically, the Company's violations of federal law with regards to the operation of that plant, the impact that those violations had on the Company's sale of Paxil and Paxil CR.

110. Indeed, as outlined *infra*, GSK and/or the LLC has a history of conducting misleading and/or unlawful business activity, both prior to and during the Class Period with regards to the Company's manufacturing, marketing and distributing of prescription medication. As a result of these business activities, the maintenance of the GSK Stock Fund in the Plans was imprudent during the Class Period and Defendants breached their fiduciary duties owed to the Plan, Plaintiffs and the purported Class.

111. Defendants were not obligated by ERISA or by the Plans to discharge their duty to provide information to Participants through the mechanism of incorporation of SEC filings. Defendants could have fulfilled this duty by setting forth sufficient and accurate information in the SPDs themselves, and updating such information as appropriate. Defendants chose, however, to adopt the mechanism of incorporation of SEC filings into the SPDs, and the SEC filings contained materially false and misleading information which caused loss to the Plans and the Participants as set forth above.

[1] As discussed in **¶ Error! Reference source not found.**, on May 21, 2007 a study by Dr. Stephen Nissen was published in concluding that patients taking Avandia were at an increased risk for heart attacks.

112. At all relevant times, Defendants should have known of the material misrepresentations and omissions -- including, in particular, those filed with the SEC and incorporated by reference in the SPDs.

FACTS CONCERNING THE COMPANY'S CIDRA, PUERTO RICO PLANT

113. GSK opened a manufacturing plant in the Puerto Rican municipality of Cidra in 1969. During all times relevant herein, the plant manufactured the drugs, *inter alia*, Avandia, Avandamet, Bactroban, Paxil, Paxil CR and Thorazine.

114. On July 1, 2002, after it had spent 17 non-consecutive days inspecting the Cidra plant, the FDA[2] issued a warning letter to GSK and SB Pharmco Puerto Rico regarding certain regulatory violations at the facility. According to the July 1, 2002 letter, GSK "products Bactroban Ointment, Paxil Oral Suspension and Thorazine tablets are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, drug and Cosmetic Act; and in violation of Title 21 Code of Federal Regulations, Parts 210 & 211." These violations included:

- Failure of the quality control unit "to reject all drug products that fail to meet the established specifications; to assure that all records related to a product manufactured are adequately reviewed and that no errors that may impact the identity, strength, purity and/or safety of the drug products have occurred, or if an error has occurred that an investigation including corrective actions is performed in a timely manner";
- Failure of the Company to have procedures in place to prevent microbial contamination of products as required by the Code of Federal Regulations;

[2] The United States Food and Drug Administration (the "FDA") is an agency within the federal Department of Health and Human Services. Among others things, as enunciated on its website, the "FDA is responsible for protecting the public health by assuring the safety, efficacy, and security" of prescription pharmaceuticals such as those manufactured, marketed and distributed by GSK and its subsidiaries.

- Failure, in production and process controls, to assure batch uniformity and integrity of drug products and to assure that the production and process are adequate to consider the process as validated and in conformance with the specifications as required by the Code; and
- A failure to conduct investigations in a timely manner and to take corrective actions to prevent recurrence.

115. In conjunction with the enunciated code violations, the FDA provided the Company with specific examples of problems with products produced at the Cidra plant, including, for example, bacterial contaminations of its Bactroban Ointment product and uniformity problems with its Paxil pills, which could split apart or deliver inconsistent amounts of medication.

116. According to the *Eckard* Action, defined *infra*, there was a history of violations of federal rules and/or regulations at the Cidra plant. In fact, a "report prepared by Cheryl D. Eckard ["Eckard"] for GSK senior executives in April 2003 [referred to herein as "the April 2, 2003, report"] listed six areas in which Cidra had been repeatedly cited by the FDA for cGMP [defined *infra*] violations since 1991, namely documentation, process validation, laboratory investigations, other investigations, sterile facility and computer validation." *United States ex rel. Cheryl Eckard v. GlaxoSmithKline*, Case No. 1:04-cv-10375-JLT (D.Mass. Feb. 25, 2004) (the "*Eckard* Complaint" or the "*Eckard* Action") at ¶58.

117. Indeed, according to the initial *Eckard* Complaint:

> An FDA inspection conducted at Cidra from March 29, 2001 to July 6, 2001, found significant cGMP [*defined infra*] deficiencies such as process validation deficiencies in Paxil OS (Oral Suspension) batches, inadequate out-of specification ("OOS") and complaint investigations, inadequate laboratory controls, inadequate media fills, non-stability indicating analytical methods

> (i.e., inadequate testing to ensure that drug products could meet their purported shelf life) and deficiencies related to the aseptic (i.e. sterile) filling operation (relating to the production of injectable drugs). The FDA investigator who conducted this inspection initially recommended issue of a Warning Letter; however, following a meeting with GSK the FDA judged GSK's response adequate and inspection was classified VAI (Voluntary Action Indicated). An FDA-483 was issued to GSK on or about July 6, 2001.

Id. at ¶59.

118. An FDA-483 is a form utilized by FDA inspectors to list observations to later be provided to company officials upon conclusion of an inspection. Essentially, the form identifies deviations from current Good Manufacturing Practices ("cGMPs") found by the FDA inspector at the company (or its laboratory, manufacturing and/or distribution facilities). According to the FDA's website:

> Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards.

119. According to the *Eckard* Action, "[o]n or about October 22, 2003, GSK announced in an SEC filing that in October 2003 the FDA had begun an investigation of its manufacturing facility in Cidra, Puerto Rico." *See Eckard* Action, Dkt No. 1 at ¶100; Dkt No. 65 at ¶84. With regards to this issue, the Form 6-K, Report of Foreign Issuer, filed by GSK with the SEC on October 22, 2003 for the quarter ended September 30, 2003, merely stated:

> In October 2003 the US Food and Drug Administration (FDA) began an investigation of the Group's manufacturing facility in Cidra, Puerto Rico. The Cidra site is engaged in tableting and

> packaging for a range of GlaxoSmithKline products – primarily for the US market – including Paxil, Paxil CR, Coreg, Avandia and Avandamet. Although the FDA has not informed the Group of the specific nature of its investigation, records provided to the FDA focus on manufacturing at the site in 2001 and 2002. The Group has received no indication that ongoing supply from the site will be affected. The Group is fully co-operating with the investigation and is working to clarify the specific nature of the FDA's concerns.

120. However, according to the Company's 2009 Annual Report, "[i]n October 2003, the US federal government executed a search warrant at the Cidra facility and seized records relating to the manufacturing operations at the site." Further, as reported by *American Medical News* (amednews.com), published by the American Medical Association (the "AMA") on November 8, 2010, "[t]he FDA seized $2 billion worth of drugs from the Cidra facility in October 2003 and February 2005, according to Eckard's attorneys."

121. As noted *supra*, the initial *qui tam Eckard* Complaint was filed on February 25, 2004. She commenced the civil lawsuit in the name of and on behalf of the United States of America and States of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee, Texas, and Virginia, along with the District of Columbia, in the United States District Court for the District of Massachusetts (the "District of Massachusetts"). *See Eckard* Action, Dkt. No. 1. According to the *Eckard* Complaint, Eckard, who holds a B.A. in Chemistry, is an expert "in Code of Federal Regulations, Part 21, compliance" and "on the technical, legal, regulatory and compliance aspects of the pharmaceutical Good Manufacturing Practices and quality systems regulations relating to the development, manufacture, packaging, testing, holding and distribution of drug products." She worked for GSK from 1992 through 2003, holding the title of Manager of Global Quality Assurance. *See Eckard* Action, Dkt No. 1 at ¶6.

122. According to the initial *Eckard* Complaint, in response to the FDA's Warning Letter, outlined *supra*, on or about August 7, 2002, Eckard "was assigned by GSK headquarters in Research Triangle Park, NC ["RTP"], to lead the Warning Letter Recovery Team in Cidra." *Id*. at ¶65. Her "role was to coordinate and oversee the work of Compliance Action Plan Team Leaders who were assigned to each functional area, including Materials, Equipment, Facilities/Utilities, Validation, Laboratory, Computer Validation, Quality Assurance, Production, and Calibration." *Id*. at ¶66.

123. On or about August 14, 2002, after receiving an internal report outlining "compliance issuance that the FDA had not identified in its recent inspections," Eckard recommended "GSK stop shipping all product from the Cidra plant, stop manufacturing product for two weeks in order to investigation and resolve the issues raised and the impact on released batches, and notify the FDA about the product mix-ups." *Id.* at ¶¶67-69. Eckerd's concerns and recommendations were relayed to Steve Plating, who, at the time, was Vice President, N.A. of GSK.

124. On or about August 15, 2002, after returning to GSK headquarters in RTP, Eckard reported her concerns via telephone to Janice Whitaker, then GSK's Senior Vice President for Global Quality. *See id.* at ¶¶16, 70. According to Eckard, she "gave Whitaker the information that she had received at Cidra, including that Cidra had lied to the FDA. She recommended that GSK stop shipping all product from the Cidra plant, stop manufacturing product for two weeks in order to investigation and resolve the issues raised and the impact on released batches, and notify the FDA about the product mix-ups." *Id.* at ¶70.

125. In addition, according to the *Eckard* Complaint:

> Eckard reminded Whitaker of GSK's promise to the FDA at the meeting on July 17, 2002, that GSK would immediately notify the

> FDA if any problems were found that could present a public health risk. Eckard told Whitake that she believed the Cidra plan was headed for a Consent Decree if the problems were not handled with speed and integrity. Eckard left a copy of the Martinez presentation on Whitaker's desk.

Id. at ¶71.

126. The *Eckard* Complaint further alleged that:

> In September 2002, Eckard spoke by phone with David Pulman ("Pulman"), who was then Vice President of Manufacturing and Supply for North America. Pulman was promoted to President, Global Manufacturing and Supply in December 2002. Plating had provided Pulman with a copy of the Martinez presentation on or about August 15, 2002. Pulman's overriding concern was to make the Cidra plant ready for The FDA reinspection to commence on or about October 9, 2002. As stated above, passing this inspection was a precondition to obtaining FDA approval for Avandamet and Factive. Pulman asked Eckard for specific examples of the quality problems at the plant. She gave him a few examples and later sent him, via email, a report prepared by the Director of Validation for the sterile facility at GSK's Barnard Castle plant in the United Kingdom, who had been brought in to review validation in the sterile suite in Cidra. His report was scathing. Eckard told Pulman that nothing had improved at the Cidra plan since her report to Plating or about August 24, 2002.

Id. at ¶72.

127. Eckard contended that, throughout the remainder of 2002 and into April 2003, she urged GSK managers to correct the quality and compliance problems at the Cidra plant. *See id*. at ¶73. The GSK managers failed to take any action and she, in response to the findings outlined in the Martinez presentation, believed that:

> . . .Whitaker, Pulman and other GSK executives were unwilling to acknowledge the gravity of the cGMP violations at the Cidra plant and to take the action that Eckard had recommended in part because the FDA had indicated that it would not consider approvals for Avandamet and Factive until the Warning Letter issues were resolved, and such approvals were unlikely to be obtained if the FDA were aware of the gravity of the quality deficiencies at the Cidra plant. Once the objective of approval for Avandamet was achieved, GSK and Cidra management alike lost

> interest in correcting the deficiencies at the Cidra site and resumed their focus on maximizing productivity at the plan. As stated above, the Cidra plan manufactures $5.5 billion of GSK's product and is the most important of all GSK's plants worldwide.

Id.

128. The FDA approved Avandamet on October 8, 2002 and approved Factive on April 4, 2003. *See id.* at ¶74. Avandamet is a fixed-dose combination of metformin and rosiglitazone prescribed for type 2 diabetes patients.

129. In late 2003, Eckard was advised by Jose Luis Rosado, President of SB Pharmco Puerto, *Inc. a*nd General Manager of the Cidra plant (until his resignation in April 2003), and by Adalberto Ramirez, at the time Director of Solid Manufacturing and Packaging, that they wanted to take over leadership of the correction of Cidra's systemic quality assurance and compliance problems in response to the Warning Letter. *See id*. at ¶¶21, 23, and 75. "Following a meeting with Plating, it was agreed that Ramirez would lead the effort and Eckard would play an 'oversight' role and report to Plating." *Id.*

130. However, Eckard claimed that:

> In or about February 2003, [she] learned that Ramirez had repeatedly lied to her about the status of work in the written and verbal progress reports he had provided to her since assuming control of Warning Letter recovery. She also learned that the Compliance Teams had been disbanded immediately after the FDA's October reinspection and the approval of Avandament, and that Rosado, Ramirez and Lopez [at the time the Cidra Director of Quality] had misrepresented the true status of the Warning Letter to the FDA at [a] January 24, 2003 meeting . . .. Eckard reported these concerns to Plating to her immediate boss, Diane Sevigny ('Sevigny"), Director of Global Quality Assurance for North America Pharma.

Id. at ¶¶22, 78; *see also* ¶¶110-11, 114, 117, 124, and 127.

131. Eckard further alleged that:

> Following her findings in the February 2003 RTP audit and her discovery that Ramirez had lied to her about the status of progress by the Compliance Action Teams, Eckard told Sevigny in substance that she would not participate in a cover-up of the quality assurance and compliance problems at Cidra and would not take part in any further meetings with the FDA about the Cidra plant. During this period and thereafter, Eckard and Sevigny were in frequent and increasing conflict about GSK's management of the quality and compliance problems at Cidra.

Id. at ¶80.

132. On or about April 2, 2003, Eckard delivered a memorandum to seven senior managers detailing certain Cidra high risk compliance problems. *See id*. at ¶83. She never received a response to the memorandum from any of the managers. *See id*. at ¶84.

133. Also, in early April 2003, Eckard learned that certain "persons at the Cidra plant were skimming product during manufacture, including reject product, and diverting the product to Latin America." *Id*. at ¶85. However, after a very short investigation of the allegations, "[i]n or about April or May of 2003, GSK closed its internal investigation for lack of sufficient evidence." *Id*. at ¶95.

134. In early May 2003, Eckard received a phone call from Human Resources ("HR") advising her that she was being offered a "redundancy package," which she rejected. HR responded by instructing her to remain, for two weeks, unpaid. Then, in late May, HR asked her to attend a meeting at which the Vice President of HR for Global Operations "formally presented the redundancy package to her, took her security badge, and escorted her from the premises." *Id.* at ¶96.

135. In late July 2003, Eckard alleged, she telephoned the then-CEO, Defendant Garnier in the United Kingdom to address Cidra's quality and compliance problems. However, defendant Garnier refused to respond to her. *See id.* at ¶97. She also called GSK's general

counsel in the United States regarding the issue, but was referred to the Vice President for Compliance. *See id.*

136. On or about July 14, 2003, Eckard spoke with the Vice President of Compliance and "detailed the serious quality assurance and compliance problems at Cidra, including the product diversion allegations." *Id.*

137. Eckard then, on August 27, 2003, participated in a teleconference with other GSK compliance personnel regarding the quality assurance and compliance problems issues. *See id.* at ¶98.

138. Later that day on August 27, 2003, after discerning that "GSK was unlikely to take any corrective action," Eckard spoke with Compliance Officer Carmelo Rosa of the FDA's San Juan District Office. *Id.*

139. On October 3, 2003, Eckard followed-up her August 27th conversation with FDA Officer Rosa and informed him that "GSK did not intend to take any corrective actions as a result of her report." *Id.* at ¶99.

140. As noted *supra*, on October 22, 2003, GSK announced in a Form 6-K filed with the SEC that, during that month, the FDA had begun an investigation of the Cidra plant.

141. The *Eckard* Action alleges that "GSK routinely and egregiously violated the cGMPs and related laws and regulations at its Cidra plant" and "lied to the FDA in order to conceal those violations, including lies contained in documents responding to consumer complaints." *Id.* at ¶46. According to the *Eckard* Action, Eckard sought "to recover damages and civil penalties in the name of the United States and the states for the violations alleged [t]herein" and "damages on [Eckard's] behalf for retaliatory discharge under 31 U.S.C. § 3730(h)." *Id.* at ¶¶7-8

142. The *Eckard* Complaint alleges, in part, that:

> . . . In response to a Warning Letter citing violations of the cGMPS, GSK concealed systemic quality assurance problems at Cidra that, if known to the FDA, would have delayed or precluded the approval of new profitable drugs manufactured at the plant. In addition, GSK failed adequately to investigate an allegation of product diversion at the plant that, on information and belief, led to the distribution of reject drug products to the United States market. . . .

Eckard Action, Dkt No. 1 at ¶46.

143. More specifically, the *Eckard* Complaint alleges that:

> For example, GSK released to the United States market from its Cidra plant:
>
> a. Drug product that was mixed up with drug product of a different type or strength, e.g., 30 mg and 10 mg tablets of an anti-depressant mixed in the same bottle, and 12.5 and 6.25 mg tablets of a heart medication mixed in the same bottle;
>
> b. A diabetes medication that was sub-potent and/or super-potent;
>
> c. An antibiotic ointment used to treat a skin infection common in small children that was contaminated with a microorganism associated with bacteranemia, urinary tract infections, meningitis, would infection, and peritonitis;
>
> d. An injectable drug used to treat nausea and vomiting in patients undergoing chemotherapy that was contaminated with micro-organisms.

Id. at ¶47.

144. According to the *Eckard* Complaint:

> GSK's violations of the cGMPs and chronic quality assurance problems went to the heart of Cidra's manufacturing systems. As further detailed [in the Complaint] below, they included:
>
> a. Product mix-ups, i.e., a drug of a different type or strength found in the same bottle [];
>
> b. Inadequate investigation of out-of specification results detected during laboratory testing [];

c. Inadequate process validation and non-existent validation review processes for some products [] ;

d. Inadequate or non-existent calibration of equipment and instruments and incomplete investigations relating to equipment to be found to be out-of-calibration [];

e. Overdue process investigations, at times numbering in the hundreds [];

f. Understaffing in the Quality Assurance Unit []:

g. Poor documentation quality, including unsigned, undated and/or lost or missing validation, investigation and change control documents, hundreds of standard operating procedures overdue for revision [];

h. Contamination in products manufactured in the sterile facility, including Kytril injection and Bactroban ointment [];

i. Substandard quality control of the plant's water systems, resulting in build up of stagnant wate and microbial contamination [];

j. Manufacturing areas purportedly clean equipment that repeatedly failed routine environmental testing and exhibit microbial contamination [];

k. Destruction of internal audit reports immediately after discussion with the responsible personnel, contrary to GSK policy and industry practice requiring 3 year retention [];

l. Serious deficiencies in the functioning of the Microbiology Laboratory, where testing of products and equipment for contamination by objectionable organisms is conducted [];

m. Substandard air handling systems not meeting cGMP standards and creating the potential for cross contamination [];

n. Inadequate monitoring to ensure containment of cytotoxic product (Topotecan, a chemotherapy drug) manufactured in the facility [];

o. Various other cGMP issues, including inadequate identification, control and storage of drug materials, waste and cleaning agents, poor disinfection procedures, leaking equipment, and inadequate verification of product labels [].

Id. at ¶¶48-49, *see also* ¶¶101-138.

145. The *Eckard* Complaint also alleged that GSK violated the False Claims Act, because, *inter alia*:

> The defendants manufactured, processed, packed an/or held drugs at the Cidra plant that were adulterated with the meaning of 21 U.S.C. §§ 351(a)(2)(A) and (B), in that the drugs were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health, and/or methods used in, and/or the facilities or controls used for, the manufacture, processing, packing and/or holding did not conform to and/or were are operated or administered in conformity with the cGMPs to assure that such drugs met the requirements of the FDC Act as to safety and had the identify and strength, and met the quality and purity characteristics, that they were represented to possess. As a result, the drugs did not meet the safety and effectiveness standards required for approval and distribution in interstate commerce under the FDC Act and for payment by Medicaid, the VA and other government health programs under the Social Security Act, including 42 U.S.C. 1396r-8(k). Therefore, claims for those drugs were false.

Id. at ¶50.

146. On March 4, 2005, according to an FDA press release, representatives of the United States government again entered the Cidra plant. This time, the U.S. Marshals seized lots of Paxil CR and Avandamet. As noted *supra*, Avandamet is a fixed-dose combination of metformin and rosiglitazone prescribed for type 2 diabetes patients. Paxil CR is prescribed to treat depression and panic disorder.

147. According to that FDA press release, the U.S. Marshals seized the drugs because "[m]anufacturing practices of the two drugs . . . failed to meet the standards laid out be FDA that ensure product safety, strength, quality and purity." The press release further stated, in relevant part, that:

> The agency is concerned that GSK's violation of manufacturing standards may have resulted in the production of poor quality drug products that could potentially pose risks to consumers Among the

> violations noted during FDA's latest inspection was that the finding that the Paxil CR tablets could split apart and patients could receive a portion of the tablets that lacks any active ingredient and does not have the intended controlled-release effect. Additionally, FDA found that some Avandamet tablets did not have an accurate does of rosiglitazone, an active ingredient in this product.
>
> The seizures follow warrants issued by the U.S. District Courts for the District of Puerto Rico and Eastern District of Tennessee. The seizures were executed today by the U.S. Marshals Service at GSK's Cidra, Puerto Rico manufacturing facility, its Knoxville Tennessee distribution facility, and a Puerto Rico distribution facility. GSK has voluntarily recalled some of the affected lots of Paxil CR and Avandamet; however, it has failed to recall all affected lots of these products. This failure on the part of GSK resulted in today's seizures by federal authorities.

148. On April 28, 2005, the FDA issued another press release stating that GSK had signed a consent decree with the FDA to correct its manufacturing deficiencies at the Cidra plant (the "Consent Decree"). The release stated:

> The U.S. Food and Drug Administration (FDA) today announced that GlaxoSmithKline, Inc. (GSK), (through its U.S. subsidiaries SB Pharmco Puerto Rico, Inc., GlaxoSmithKline Puerto Rico Inc., and SmithKline Beecham Corporation), has signed a consent decree with FDA to correct manufacturing deficiencies at its Cidra, Puerto Rico facility.
>
> FDA is concerned that GSK's violation of manufacturing standards may have resulted in the production of drug products that could potentially pose risks to consumers.
>
> The Decree requires GSK to post a penal bond of $650,000,000 contingent upon GSK's either successfully reconditioning drugs seized in March 2005 or destroying them and paying costs to the government.
>
> "The consent decree shows that FDA is serious about enforcing the manufacturing standards essential for safe and effective prescription drugs," said John Taylor, FDA Associate Commissioner for Regulatory Affairs. "It should also reassure the American people that we are doing everything we can to preserve the integrity of the American drug supply."

> FDA's last inspection found Paxil CR tablets, approved to treat depression and panic disorder, could split apart. This deficiency could cause patients to receive a portion of the tablets that lacks any active ingredient, or alternatively a portion that contains an active ingredient and does not have the intended controlled-release effect. Additionally, FDA found that some Avandamet tablets, used to treat Type II diabetes, did not have an accurate dose of rosiglitazone, an active ingredient in this product.
> The FDA urges patients who use these two drugs to continue taking their medication and to talk with their health care provider about possible alternative products until the manufacturing issues have been resolved.
>
> Under the terms of this decree the company has agreed to take measures to ensure that its Cidra facility and the two drugs, Paxil CR and Avandamet, fully comply with current Good Manufacturing Practice (cGMP) requirements and to ensure that ongoing shipments have the quality attributes they are required to possess. The decree also requires that all corrections and the firm's compliance with cGMP requirements be certified by a third-party expert. Additionally, FDA will continue to monitor these activities through its inspections.
>
> The Decree was presented yesterday for consideration by the United States District Court for the Eastern District of North Carolina. The Decree will take effect after it has been signed and entered by the Court.

149. On June 12, 2006, an Amended Complaint was filed in the *Eckard* Action (the "*Eckard* Amended Complaint"). *See Eckard* Action, Dkt. No. 18. Among other things, the *Eckard* Amended Complaint added that the litigation was also being brought on behalf of the States of Indiana, Michigan, and New Hampshire, and the cities of Chicago and New York.

150. According to the March 2007 Dimensions Newsletter:

> All manufacturing supply divisions and functions have contributed to the financial performance of [Global Manufacturing & Supply ("GMS")] through sound technical management and careful control of operational and discretionary expenditure, without compromising supply security or quality.

151. As outlined in the March 2007 issue of the Dimensions Newsletter, the newsletter's editorial team includes U.S. and United Kingdom employees who were members of

the Benefits, Employee Health Management and Compensation departments. Any Participants with suggestions, comments or article ideas were requested to send an email to a GSK address. The Dimensions Newsletter is "mailed to [U.S. employees] home[s] because [GSK] realize[s] that *TotalReward* involves not only [the employee], but also [the employee's] family and the significant people in [their] life."

152. On July 17, 2007, the Honorable Joseph L. Tauro, District Judge of the District of Massachusetts, issued his Order unsealing the *Eckard* Complaint, *Eckard* Amended Complaint and shortly-to-be-filed *Eckard* Second Amended Complaint (defined *infra*). The court also lifted the seal as to all other matters filed after July 17, 2007. *See Eckard* Action, Dkt. No. 32.

153. On July 23, 2007, GSK filed its assented to motion to seal, which the court promptly denied on that same day. *See Eckard* Action, Dkt. No. 33. In its assented to motion to seal, GSK maintained that:

> . . . To unseal the proceedings at this time will force the parties to commence active litigation, thus potentially interfering with the government's ability to conduct a thorough investigation and distracting the government and GSK from their joint effort to resolve this matter. Moreover, unsealing this matter will inevitably cause GSK substantial harm in the marketplace that may otherwise be avoided depending on the disposition of the government's investigation. Finally, maintaining the confidentiality of this matter will result in no harm to the Relator. Rather, the Relator will potentially avoid the burdens of proceeding with litigation and an uncertain outcome.

154. On July 24, 2007, a Second Amended Complaint was filed in the *Eckard* Action (the "*Eckard* Second Amended Complaint"). *See Eckard* Action, Dkt. No. 34. Among other things, the *Eckard* Second Amended Complaint added that the litigation was also being brought on behalf of the States of New Mexico and New York.

155. On October 17, 2008, a Third Amended Complaint was filed in the *Eckard* Action (the "*Eckard* Third Amended Complaint"). *See Eckard* Action, Dkt. No. 65. Among other

things, the *Eckard* Third Amended Complaint added that the litigation was also being brought on behalf of the State of Georgia

156. Notwithstanding the allegations in the *Eckard* Action, the September 2008 Dimensions Newsletter, commenting on the six months to June 2008 performance, claimed that "GMS continues to support the commercial ambition of GSK with outstanding customer service performance, excellent quality performance and 100% support of new product launches." The newsletter was edited by GSK employees.

157. The November 2008 Dimensions Newsletter stated that the Company's "focus on quality is bringing outstanding results, with 2008 on track to being one of our most successful years ever. . . . The focus for GMS going forward is to continue to deliver strong performance, improve upon the good things that we are doing, and to respond in an agile way to the new demands that Commercial and R&D organizations place upon us."

158. In the March 2009 issue of the Dimensions Newsletter, edited by GSK employees, Defendants informed U.S. employees, including members of the purported Class, that:

> During 2008 GMS improved in every aspect of our business. We sustained strong customer service performance, including support for new product launches. We launched at least one new product each month during 2008 (except August), in either the U.S. Europe or Japan. ***Our quality performance was tremendous, our inspection performance was fabulous*** and our health and safety performance is improving all the time.

(Emphasis added).

159. The September 2009 Dimensions Newsletter, edited by GSK employees, stated that:

> GMS is performing well. Increased volumes and strong cost control programs are having a positive impact on our financial performance.

160. However, in reality, the Cidra plant ceased operations on July 30, 2009, and the operational staff was released on September 30, 2009. According to an October 26, 2010 press release issued by GSK concerning the resolution, outlined below, of pending criminal and civil lawsuits regarding the Cidra plant, it "was closed in 2009 due to declining demand for the medicines made there." GSK's stated reason for the closure of the plant is misleadingly unrealistic in light of the extensive and significant problems at the Cidra plant, as outlined herein.

161. Plaintiffs are not aware of any disclosures by Defendants, prior to the issuance of its 2009 Annual Report, that the FDA seized drugs from the Cidra plant in or about October 2003, as outlined *supra*.

162. On July 15, 2010, as also outlined *supra*, GSK issued a press release stating, in part, that:

> GlaxoSmithKline (GSK) today announces that it expects to record a legal charge for the second quarter of 2010 of £1.57billion ($2.36 billion) (equating to an after tax cost of £1.35 billion). The charge includes settlements, agreements in principle to settle, and other provisioning for long-standing legal cases.
>
> The settlements and agreements in principle to settle include an investigation by the US Government into the company's former manufacturing site at Cidra, Puerto Rico; product liability and anti-trust litigation relating to Paxil (paroxetine), and product liability cases regarding Avandia (rosiglitazone) and other products.

163. On October 21, 2010, Carmen M. Ortiz, United States Attorney for the District of Massachusetts, sent a letter (the "Ortiz Letter") to attorneys for the GSK subsidiary SB Pharmco Puerto Rico, Inc. The Ortiz Letter outlined the terms of the settlement agreement (the "Cidra Agreement") between the U.S. Department of Justice (the "DOJ") and the defendant in the *USA v. SB Pharmco Puerto Rico, Inc*. matter.

164. According to the Ortiz Letter, "[a]t the earliest practicable date SB Pharmco shall waive the indictment and plead guilty;" specifically stating, in part, as follows:

> Count One of the Information charges that from in or about March 2003 to October 2004, SB Pharmco introduced for delivery into interstate commerce various quantities of adulterated drugs Paxil CR, Avandamet, Kytril and Bactroban in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 351(a)(2)(B). SB Pharmco expressly and unequivocally admits that it committed these offenses and further admits that it acted with the intent to defraud or mislead. Defendant expressly and unequivocally further admits that it is in fact guilty of this offense, and agrees that it will not make any statements inconsistent with this explicit admission.

165. The Cidra Agreement was signed by the relevant parties between October 21 and 26, 2010.

166. The terms of the Cidra Agreement became public on October 26, 2010, when the DOJ issued a press release entitled "GlaxoSmithKline Will Plead Guilty and Pay $750 Million to Resolve Manufacturing Deficiencies at Puerto Rico Plant." The press release stated, in relevant part, as follows:

> The Justice Department announced today that SB Pharmco Puerto Rico, Inc., a subsidiary of GlaxoSmithKline, PLC ("GSK"), has agreed to plead guilty to charges relating to the manufacturing and distribution of certain adulterated drugs made at GSK's now-closed Cidra, Puerto Rico, manufacturing facility. The resolution includes a criminal fine and forfeiture totaling $150 million and a civil settlement under the False Claims Act and related state claims for $600 million.
>
> The drugs, manufactured at the plant between 2001 and 2005, are Kytril, Bactroban, Paxil CR, and Avandamet. Kytril is a sterile anti-nausea medication. Bactroban is a topical anti-infection ointment commonly used to treat skin infections. Paxil CR is the controlled release formulation of the popular anti-depressant drug, Paxil, and Avandamet is a combination Type II diabetes drug. The criminal information filed today alleges that SB Pharmco's manufacturing operations failed to ensure that Kytril and Bactroban finished products were free of contamination from microorganisms. It is further alleged that SB Pharmco's manufacturing process caused Paxil CR two-layer tablets to split.

The splitting, which the company itself called a "critical defect," caused the potential distribution of tablets that did not have any therapeutic effect and tablets that did not contain any controlled release mechanism.

According to the information, Avandamet tablets manufactured by SB Pharmco did not always have the FDA-approved mix of active ingredients, and, as a result, potentially contained too much or too little of the ingredient with the therapeutic effect. Finally, it is alleged in the criminal information that SB Pharmco's Cidra facility suffered from longstanding problems of product mix-ups, which caused tablets of one drug type and strength to be commingled with tablets of another drug type and/or strength in the same bottle.

Under the plea agreement, the company will pay a criminal fine of $150 million including forfeiting assets of $10 million. A date for the plea hearing has not been set.

Under the civil settlement, GSK has agreed to pay an additional $600 million to the federal government and the states to resolve claims that it caused false claims to be submitted to government health care programs for certain quantities of adulterated Kytril, Bactroban, Paxil CR and Avandamet. The government contends that GSK knowingly caused false and/or fraudulent claims to be submitted to, or caused purchases by, the Medicaid Program and the other federal health care programs, by selling drugs that did not meet the quality specified in the drugs' NDAs.

The federal share of the civil settlement amount is $436,440,000 and GSK will pay up to $163,560,000 to states that opt to participate in the agreement.

* * *

FBI SAC Richard DesLauriers said, "The completion of this investigation reflects law enforcement's efforts to make companies like GlaxoSmithKline accountable for knowingly manufacturing and releasing defective products to millions of adults and children suffering from diabetes, depression, and skin infection. To avoid lost profits, GlaxoSmithKline intentionally disregarded the potential harmful effects of these defective drugs on consumers. The FBI will continue to work collaboratively with our law enforcement partners to identify individuals and companies who seek to line their pockets at the expense of the health care system and safety of each of us."

* * *

> The civil settlement resolves one lawsuit filed in federal court in the District of Massachusetts under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery. As part of today's resolution, the whistleblower, Cheryl Eckard, will receive approximately $96 million from the federal share of the settlement amount.

(emphasis added).

167. As reported by the *Chemical & Engineering News* ("*C&EN*") on October 29, 2010, in response to the Cidra Agreement, Elpidio Villarreal, GSK's head of global litigation, stated: "We regret that we operated the Cidra facility in a manner that was inconsistent with cGMP requirements." The Company stated that it had not received an FDA warning since 2002 at the Cidra plant.

168. The *C&EN* further reported that Denise Smart, a regulatory compliance expert and co-founder of Smart Consulting Group, noticed a distinct increase in the number of FDA warning letters issued in recent months. Denise Smart also stated, in pertinent part, as follows:

> And I have not seen anything like the GSK settlement, where the government is bringing both criminal fines and civil penalties for cGMP violations. They are taking cGMP enforcement to a new level.

169. GSK agreed to pay $600 (of the $750) million to the federal and state governments to resolve allegations that it caused false claims to be submitted to government health care programs for certain quantities of adulterated Kytril, Bactroban, Paxil CR, and Avandamet, a derivative of Avandia. The U.S. contends that GSK sold certain batches, lots, or portions of lots of drugs, the strength of which differed materially from, or the purity or quality of which fell materially below, the strength, purity, or quality specified in the drugs' FDA applications or related documents, and then GSK thereby knowingly caused false and/or

fraudulent claims to be submitted to, or caused purchases by, Medicaid and the other federal health care programs.

170. The federal share of the $600 million civil settlement amount is $436,440,000, and GSK will pay up to $163,560,000 to States that participate in the Cidra Agreement.

171. Additionally, as part of the $750 million settlement, the Company paid criminal fines of $150 million, the largest such payment ever by a manufacturer of adulterated drugs, including forfeiting assets of $10 million. The share to the whistle-blower will be $96 million, one of the highest such awards in a health care fraud case.

172. According to an article in *The New York Times*, dated October 26, 2010, the FDA and the inspector general of the Health and Human Services Department both announced that they would pursue charges against GSK executives personally under a strict liability provision of the law -- something that had not been done since 2007.

FACTS CONCERNING PAXIL

173. The FDA approved Paxil for the treatment of depression, panic, obsessive compulsive disorder, post traumatic stress disorder, social anxiety disorder, premenstrual dysphoric disorder, and general anxiety disorder in adults. It was not approved for any condition or illness in children and adolescents.[3] SmithKline first began selling Paxil, and other related Paroxetine products, in the United States market in 1992. It is a member of a class of drugs known as the selective serotonin reuptake inhibitors ("SSRIs"). At that time, the other SSRIs

[3] The FDA also provides for physicians to prescribe FDA-approved drugs for conditions or diseases for which FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines that the drug in question is an appropriate treatment for an individual patient. In the United States in the 2002 year alone, this practice, referred to as "off-label" use, resulted in doctors writing approximately 2.1 million paroxetine prescriptions for children and adolescents, with nearly 900,000 of those prescriptions being written for minors with a primary diagnosis of mood disorder.

marketed in the United States, by Paxil's competitors, were Prozac and Zoloft, which were manufactured, marketed and distributed by Eli Lilly & Company and Pfizer, respectively. As outlined *supra*, among other things, before and during the Class Period, Paxil was manufactured at the Company's Cidra plant.

174. In promotional literature, advertisements and drug information provided to doctors, GSK claimed that "Paxil belongs to a class of medications called SSRIs, which have not been shown to be associated with addiction."

175. However, according to *Current Problems in Pharmacovigiliance*, Volume 19, published February 1993, the Committee on Safety of Medicines ("CSM"), Great Britain's counterpart to the FDA, reported 78 cases of withdrawal after discontinuation of paroxetine, reporting that such reactions have been reported more often with paroxetine than with other SSRI's.

176. Further, at the American Psychiatric Association's annual meeting held in San Francisco, between May 22 and 27, 1993, just five months after Paxil entered the U.S. marketplace, Dr. M.J. Stoker, then of the SmithKline CNS [Central Nervous System] Therapeutic Unit, Clinical Research and Development based in Surrey, United Kingdom, and Professor L. Eric made a presentation entitled "A Comparison of Withdrawal Effects Following Discontinuation of Paroxetine and Imipramine." In that presentation, Dr. Stoker and Professor Eric contradicted GSK's, then SmithKline's, representations regarding paroxetine withrdrawal. In fact, conducting two-week tapering regimes for 186 patients in six to 12 week double-blinded comparative studies for both low and high dose groups, the study's authors found that Paxil's low dose group actually fared worse than the high dose group, suffering a 42% withdrawal rate, as opposed to 38% in the high dose group. Both of these withdrawal rates occurred

notwithstanding the fact that a tapering regime was initiated during reductions of patients' dosage. An imipramine patient group was also studied. The imipramine group had a lower incidence of withdrawal than either paroxetine group. This report occurred five months after Paxil entered the U.S. market. Plaintiffs allege that SmithKline did nothing in response to this information.

177. On June 2, 2004, the then-State of New York Attorney General, Elliott Spitzer, filed a civil lawsuit against GSK alleging that the Company had suppressed adverse studies relevant to use of Paxil to treat children and adolescents with depression. According to *Psychiatric News*, Volume 39, Number 13, dated July 2, 2004:

> GSK's chief executive officer, Jean-Pierre Garnier, immediately denied the charges, adding that lawsuits, particularly in the United States, are "becoming an outrageous cost of doing business." Paxil is GSK's biggest money maker.

178. *Psychiatric News* further reported that:

> Spitzer alleges that "GSK has allowed positive information about pediatric use of paroxetine to be disclosed publicly, but has withheld and concealed negative information concerning the safety and efficacy of the drug as a treatment for pediatric MDD [major depressive disorder]."
>
> While it conducted five trials of the antidepressant's efficacy in children and adolescents, it published data from only one of them, he said.
>
> By failing to disclose important clinical information to physicians, the company has prevented them "from properly and independently exercising their professional judgment on behalf of their child and adolescent patients," according to the suit. At press time GSK has not responded to requests for comment from Psychiatric News. In a June 10 press release, the company said that its policy "is to ensure transparency of the clinical data the company collects on its marketed medicines. Specifically, we endorse the PhRMA [Pharmaceutical Research and Manufacturers of America] principles that call for timely publication of meaningful trial results."

GSK promised to make summaries of nine studies it funded of Paxil's safety and efficacy in children and adolescents available on its Web site, which it did on June 14. Spitzer applauded GSK's willingness to make these available to the public and physicians, saying that he hoped this spurs other pharmaceutical firms to follow suit.

Cover-Up Alleged

In his suit, Spitzer cites documentation produced by GSK indicating that the company planned to take steps to manage selectively any releases of data on Paxil clinical trials, so that evidence of ineffectiveness or harm was not disseminated.

He also charges that GSK "misrepresented" the drug's efficacy in treating adolescent depression when the company briefed its sales representatives, whose job is to convince physicians to prescribe the medication. The company supplied the sales staff with a quote touting Paxil's" REMARKABLE efficacy and safety in the treatment of adolescent depression" when, Spitzer says, none of the studies GSK conducted on the antidepressant's efficacy in this population demonstrated such a conclusion.

In addition, Spitzer alleges misrepresentation in the "Medical Information Letters" GSK sent to physicians about Paxil's effectiveness in children and adolescents with depression and failed to cite a study in which the drug turned out to be less efficacious than placebo. Through these actions, the suit charges, the company "controlled physicians' access to negative information about paroxetine as a treatment for MDD in children and adolescents...."

The consequences of GSK's marketing decision, the suit concludes, is that physicians were "misled and deceived" and thus unable to evaluate the prescribing information they need to provide optimal care for their patients.

Spitzer wants the court to enjoin GSK permanently from continuing the" deceptive, fraudulent, and unlawful practices alleged" in his suit and to order the company to "pay restitution and damages to all aggrieved consumers" to include "all profits from the sale of Paxil or Paxil CR in the State of New York for a child.

179. Shortly thereafter, on August 5, 2004, *The Wall Street Journal* published an article reporting that new FDA analysis confirmed the link between SSRIs and suicidal tendencies in minors.

180. On August 26, 2004, the New York State Attorney General and GSK announced the settlement between the State of New York and GSK with regards to the civil lawsuit filed on June 2, 2004. As a result of the lawsuit, GSK, as outlined in *Psychiatric News* and *supra*, released previously unpublished data about the safety and effectiveness of the antidepressant drug Paxil on the Company's website. In addition, the Company agreed to pay the State of New York $2.5 million.

181. On April 28, 2005, the FDA issued a press release entitled "[GSK] Signs Consent Decree with FDA; Agrees to Correct Manufacturing Deficiencies." According to the press release, as quoted *supra*, the "FDA's last inspection found Paxil CR tablets, approved to treat depression and panic disorder, could split apart. This deficiency could cause patients to receive a portion of the tablets that lacks any active ingredient, or alternatively a portion that contains an active ingredient and does not have the intended controlled-release effect." Under the terms of the Consent Decree, GSK agreed to, *inter alia*, ensure that its manufacture of Paxil CR fully complies with cGMP requirements.

182. According to a press release issued shortly before the start of the Class Period, on April 26, 2007, by the law firm then known as Baum, Hedlund, Aristei & Goldman, PC:

> Madison County Associate Judge Ralph Mendelsohn today approved and amended the national pediatric Paxil class settlement which will provide more payment to people who paid for Paxil for use by a minor. The case was based on documents showing that GSK had determined that Paxil failed to out-perform placebo for depressed minors yet GSK received money for Paxil prescribed to depressed minors. Class actions were filed in several courts

> seeking restitution of money paid by individuals and insurance companies or governmental entities that paid for minors' Paxil.
>
> In Madison County Illinois, Paxil manufacturer GlaxoSmithKline (GSK) entered into a proposed $63.8 million settlement. Lawyers representing claimants that had earlier filed similar class actions in MN and CA objected to the Madison County settlement as being unfair to the consumers in the other classes and to their lawyers, whose litigation greatly contributed to the proposed settlement.
>
> Objectors to the proposed national class settlement argued that the settlement proposal had a loophole that prevented adequate payment to a considerable number of consumers. One of the problems with the proposed settlement was reimbursement to consumers who could not (or for privacy reasons would not) provide documentation of their out of pocket expenses for Paxil purchases for a minor. This potentially substantial group of class members would only receive $15 each, and GSK limited the fund available to pay such claimants to $300,000, thus disposing of a potentially large number of claimants for just $300,000. This would result in underpayment by GSK to the class.
>
> Under the new approved terms, claimants who cannot provide documentation of their Paxil purchases for a minor will receive up to $100 by signing a claim form under penalty of perjury. Moreover, the team of lawyers representing objectors to the proposed settlement were able to negotiate the removal of the $300,000 cap in addition to the increased individual payment. This uncapping makes available more payments to a larger portion of potential claimants, thus making the settlement more fair and GSK's overall payout more adequate.

183. On June 27, 2005, in a Form 6-K filed with the SEC, GSK announced that Paxil CR was again available in the U.S. marketplace.

184. On January 29, 2009, GSK reported, in part, that:

> GlaxoSmithKline plc (GSK) today announced that it will record a legal charge in the fourth quarter of 2008 of $400 million (£278 million) relating to an ongoing investigation initiated by the US Attorney's Office in Colorado into the Group's US marketing and promotional practices for several products for the period 1997 to 2004. This charge is in addition to legal charges for other matters to be taken in the fourth quarter.

> This decision reflects the current status of the investigation, and is based upon the company's most recent evaluation of the matter. GSK is co-operating fully with the investigation. The ultimate liability related to the investigation may vary from the amount provided as it is dependent upon the outcome of the investigatory process and potential litigation.
>
> This charge was not included in the assumptions made by the company for provision of legal matters when determining its earnings guidance for 2008. Excluding the effect of this charge, the company's performance remains in line with its previously announced guidance of a mid-single digit percentage decline in 2008 business performance EPS at constant exchange rates.
>
> GSK now expects to incur a total legal charge in the fourth quarter of 2008 of £517 million (Q4 2007: £62 million), leading to a total legal charge for the full year of £611 million (FY 2007: £255 million).

185. As reported by Law.com, on October 14, 2009, in an article entitled "Paxil Hit With $2.5 Million Jury Verdict in Paxil Test":

> After deliberating for seven hours, a state court jury in Philadelphia found Tuesday that GlaxoSmithKline failed to properly warn doctors and pregnant women about risks associated with its blockbuster antidepressant Paxil. The jury awarded $2.5 million in damages to the family of Lyam Kilker, who was born with heart defects after his mother took Paxil during her pregnancy. . . .
>
> The case was the first to go to trial of more than 600 suits claiming that Glaxo hid knowledge of birth defect risks allegedly tied to Paxil. Tuesday's award in Philadelphia's Court of Common Pleas may pale in comparison to the $942 million in profits that Paxil generated for Glaxo last year, but the trial was closely watched as a test of Glaxo's vulnerability. The company released a statement saying it disagreed with the verdict and would appeal. "While we sympathize with Lyam Kilker and his family, the scientific evidence does not establish that exposure to Paxil during pregnancy caused his condition," the statement said.

186. On December 12, 2009, *Truthout* -- a 501(c)(3) nonprofit, progressive news organization) -- published an article entitled "US Kids Represent Psychiatric Drug Goldmine," which reported, in part, that:

Prescriptions for psychiatric drugs increased 50 percent with children in the US, and 73 percent among adults, from 1996 to 2006, according to a study in the May/June 2009 issue of the journal Health Affairs. Another study in the same issue of Health Affairs found spending for mental health care grew more than 30 percent over the same ten-year period, with almost all of the increase due to psychiatric drug costs.

On April 22, 2009, the US Agency for Healthcare Research and Quality reported that in 2006 more money was spent on treating mental disorders in children aged 0 to 17 than for any other medical condition, with a total of $8.9 billion. By comparison, the cost of treating trauma-related disorders, including fractures, sprains, burns, and other physical injuries, was only $6.1 billion.

In 2008, psychiatric drug makers had overall sales in the US of $14.6 billion from antipsychotics, $9.6 billion off antidepressants, $11.3 billion from antiseizure drugs and $4.8 billion in sales of ADHD drugs, for a grand total of $40.3 billion.

The path to child drugging in the US started with providing adolescents with stimulants for ADHD in the early 80s. That was followed by Prozac in the late 80s, and in the mid-90s drug companies started claiming that ADHD kids really had bipolar disorder, coinciding with the marketing of epilepsy drugs as "mood stablizers" and the arrival of the new atypical antipsychotics.

Parents can now have their kids declared disabled due to mental illness and receive Social Security disability payments and free medical care, and schools can get more money for disabled kids. The bounty for the prescribing doctors and pharmacies is enormous and the CEOs of the drug companies are laughing all the way into early retirement.

* * *

On January 29, 2009, Paxil and Wellbutrin maker, GlaxoSmithKline, announced that it would record a legal charge in the fourth quarter of 2008 of $400 million relating to an ongoing investigation initiated by the US attorney's office in Colorado into the US marketing and promotional practices for several products for the period 1997 to 2004. The government inquired about alleged off-label marketing as well as medical education programs for doctors, "other speaker events, special issue boards, advisory boards, speaker training programmes, clinical studies, and related grants, fees, travel and entertainment," according to a Glaxo annual report.

187. On December 14, 2009, *Bloomberg* published an article entitled "Glaxo Said to Have Paid $1 Billion in Paxil Suits." The article reported:

> GlaxoSmithKline Plc has paid almost $1 billion to resolve lawsuits over Paxil since it introduced the antidepressant in 1993, including about $390 million for suicides or attempted suicides said to be linked to the drug, according to court records and people familiar with the cases.
>
> As part of the total, Glaxo, the U.K.'s largest drugmaker, so far has paid $200 million to settle Paxil addiction and birth-defect cases and $400 million to end antitrust, fraud and design claims, according to the people and court records.
>
> The $1 billion "would be worse than many people are expecting," said Navid Malik, an analyst at Matrix Corporate Capital in London. "I don't think this is within the boundaries of current assumptions for analysts."
>
> The London-based company hasn't disclosed the settlement total in company filings. It has made public some accords. Glaxo's provision for legal and other non-tax disputes as of the end of 2008 was 1.9 billion pounds ($3.09 billion), according to its latest annual report. This included all legal matters, not just Paxil. The company said 112 million pounds of this sum would be "reimbursed by third-party issuers."
>
> The drugmaker has reduced its insurance coverage to contain costs, "accepting a greater degree of uninsured exposure," the annual report states. "Recent insurance loss experience, including pharmaceutical product-liability exposures, has increased the cost of, and narrowed the coverage afforded by, insurance for pharmaceutical companies generally," Glaxo said.
>
> Glaxo Comment
>
> Glaxo declined to confirm the $1 billion figure. "Paxil has been on the market in the U.S. since 1993. Like many other pharmaceutical products, it has been the subject of different kinds of litigation over the years," Sarah Alspach, a spokeswoman for Glaxo, said in an e-mailed statement. "It would be inappropriate and potentially misleading to aggregate payments in these various types of litigation."
>
> Chief Executive Officer Andrew Witty has moved to replace revenue lost to generic versions of drugs such as Paxil. Worldwide,

Paxil generated about 514 million pounds in sales last year, or 2.1 percent of the total.

Glaxo rose 21 pence to 1,324 pence in London trading after falling 4 pence earlier today. Shares have risen 12 percent in the past year.

About 450 suicide-related Paxil cases were settled. Only about a dozen haven't been, the people said. The $1 billion total doesn't include more than 600 claims that Paxil caused birth defects.

Philadelphia Trial

A Philadelphia jury on Oct. 13 found the drugmaker should pay $2.5 million to the family of Lyam Kilker, a 3-year-old boy born with a heart defect after his mother took Paxil while pregnant. Based on that outcome, an analyst estimated the company may potentially face additional verdicts in birth-defect cases waiting to be tried in Pennsylvania.

"A liability totaling $1.5 billion is possible," Savvas Neophytou, a Panmure Gordon analyst in London, wrote in a note to investors the day after the Kilker verdict. He still recommended buying Glaxo shares because a likely appeal may reduce the amount paid by the company.

In comparison, Pfizer Inc., parent of Wyeth, the maker of diet-drug combination fen-phen, has had to set aside about $21 billion to resolve about 200,000 personal-injury claims over that medicine. Merck & Co. agreed to pay $4.85 billion to resolve more than 48,000 claims over the withdrawn painkiller.

Harris Pogust, an attorney for Paxil plaintiffs, couldn't confirm the total. He said the amounts are confidential.

Paxil Is Different

"Paxil's been different from most drugs," said Pogust, a lawyer from Conshohocken, Pennsylvania, who is handling suicide and withdrawal cases. "You've had three major personal injury litigations over one drug -- the suicide, the birth defect and the withdrawal cases. To have three significant problems with one drug is really unusual."

The company had $11.7 billion in U.S. Paxil sales for nine years starting in 1997, according to documents made public this year in a Pennsylvania trial. In 2002, the year before Paxil faced generic competition in the U.S., sales of the drug there were $2.12 billion. Last year, U.S. sales had fallen to $129 million. Through

September of this year, sales were $52 million, down 52 percent from the same period in 2008.

Since at least 2003, Glaxo has faced claims in U.S. courts that some Paxil users were subjected to an undisclosed, higher risk for suicide and birth defects.

A Suicide Settlement

The suicide settlements included a suit over the death of a 14-year-old boy who had been taking Paxil for two months. The parents of Scott Cunningham, of Valparaiso, Indiana, sued after the boy hanged himself in 2001. They alleged Glaxo suppressed evidence that Paxil use was linked to the risk of suicide attempts by adolescents. Glaxo denied the allegations, according to court papers.

The family settled its suit in May, according to court filings. Family attorney Bijan Esfandiari confirmed the settlement, saying the amount was confidential.

About 150 cases over suicides by Paxil users were settled for an average of about $2 million, and about 300 over suicide attempts settled for an average of $300,000, they said. Some of the claims were resolved before suits were filed, according to the people familiar with the matter.

Glaxo has settled about 10 birth-defect cases, Sean Tracey, a Houston-based lawyer who represented the family of a child victim, said in court Dec. 2. The settlements averaged about $4 million, the people familiar with the cases said.

Unspecified Totals

The company hasn’t specified in regulatory filings the number of suicide, birth-defect and addiction cases settled.

“It’s important to disclose such settlements because it raises the red flag for both doctors and patients that there might be a problem,” said Dan Carlat, a psychiatrist at Tufts University School of Medicine in Boston who writes and edits a blog and a monthly Psychiatry Report. “It would motivate doctors to dig into the literature even more before prescribing these drugs.”

Glaxo paid an average of about $50,000 per case to resolve about 3,200 claims linking Paxil to addiction problems, the people familiar with the cases said.

In its 2008 annual report, company officials said they had reached a "conditional settlement agreement" in January 2006 with Paxil users who alleged they suffered withdrawal symptoms after taking the drug. The case, filed in Los Angeles federal court, was marked closed in court records in February.

No Liability Admission

"Glaxo did not admit liability" in the addiction settlements, the company's officials said in a March 2009 filing with the U.S. Securities and Exchange Commission.

In one of eight accords unrelated to individual suicide, addiction or birth-defect claims, Glaxo agreed in 2003 to pay $87.6 million to the U.S. and 49 states over claims it repackaged and privately labeled Paxil and another drug, Flonase, to a health maintenance organization at discounted prices.

Glaxo, denying liability, agreed in 2004 to pay $165 million to settle two antitrust suits over allegations it engaged in sham patent infringement litigation to stall approval of generic versions of the drug, court records show.

Of that total, $100 million was for direct purchasers of Paxil, such as drug wholesalers, and $65 million was for indirect buyers, the records show.

New York

In the same year, Glaxo agreed to pay $2.5 million to New York to resolve accusations the company withheld safety data about the antidepressant. The company, calling the claims unfounded, agreed to release safety studies on the medicine's effect on children.

In 2005, the company added a black-box warning to its Paxil label that the drug increased the risk of suicidal thoughts among adolescents, following a request by the U.S. Food and Drug Administration to do so.

The drugmaker agreed last year to pay $40 million to settle suits by so-called third-party payers, primarily insurance companies that reimbursed parents for their children's Paxil.

Insurers said Glaxo knew the drug "was neither safe nor effective for the treatment of depression in persons under the age of 18," U.S. District Judge Michael Davis in Minneapolis said in a September 2008 order approving the accord.

> Glaxo "denies any liability," company spokeswoman Alspach said at the time. "GSK has agreed to the settlement to avoid the costs, burdens and uncertainties of ongoing litigation."
>
> Reimbursing Parents
>
> In 2006, the company resolved similar claims by consumers for about $64 million, reimbursing parents of patients for money spent on Paxil prescriptions, in an Illinois class-action suit.
>
> Glaxo "denies any liability" in those cases, the company said in its annual report.
>
> In 2001, a jury in Cheyenne, Wyoming, ordered Glaxo to pay $6.4 million to the relatives of a man who shot his family to death and then turned the gun on himself after taking Paxil. The case was settled on confidential terms while on appeal, according to Kevin Colgan, a Glaxo spokesman.
>
> The Philadelphia case is Kilker v. SmithKline Beecham Corp. dba GlaxoSmithKline, 07-001813, Court of Common Pleas, Philadelphia County, Pennsylvania (Philadelphia).

188. According to a Law.com article dated June 23, 2010, and entitled "Paxil Litigation over Birth Defects Shifts to Settlement":

> Drugmaker GlaxoSmithKline has agreed to settle almost 200 cases in which plaintiffs allege the use of the antidepressant Paxil caused birth defects.
>
> Only one case in Philadelphia's mass tort Paxil program has gone to trial.
>
> GSK has settled every other case scheduled for trial in the eight months since a Philadelphia jury awarded a $2.5 million plaintiffs verdict in the first Philadelphia Paxil test case to go to trial.
>
> GSK started to appeal that plaintiffs verdict from October. The jury awarded only compensatory damages and no punitive damages. But GSK then decided to settle *Kilker v. SmithKline Beecham Corp. d/b/a GlaxoSmithKline* along with another 190 cases, according to an order signed by Philadelphia Common Pleas Judge Sandra Mazer Moss last week.
>
> The cases have settled for confidential amounts, said Jamie Sheller of the Sheller firm and local plaintiffs liaison counsel for the Paxil pregnancy mass tort program. GSK confirmed the settlements but

said in a spokeswoman's statement that the terms of the settlements are confidential.

Sheller estimates that up to another 100 cases, including cases that have not yet been filed, have settled. The litigation is two-thirds over, Moss and Sheller said.

The *Kilker* case was viewed by the plaintiffs mass torts bar as a leading indicator of the strength of more than 600 similar cases.

"When you're dealing with children with birth defects that's a concern for any company," Sheller said. "GSK gave it their all at that trial. ... Despite that, the plaintiffs were successful in the case and that set a tone for their analysis. Even though they mounted an excellent and strong defense they weren't able to overcome the plaintiffs' position."

The next cases in the litigation are scheduled for trial in the fall.

GSK spokeswoman Sarah Alspach said in an e-mail statement that GSK has agreed to settle some cases involving the use of Paxil during pregnancy "despite its litigation defenses, in order to avoid the costs, burdens and uncertainties of ongoing litigation."

Moss, the coordinating judge of Philadelphia's mass tort program, the Complex Litigation Center, said the philosophy of GSK "is to try and settle what they can and to settle in groups."

Moss also said the Paxil litigation has been resolving successfully in the last few months because of the cooperation between the plaintiffs and the defense bars and because GSK has not taken a stance that they're "not offering a penny."

"I think there is a great deal of cooperation between the plaintiffs and defendants," Moss said. "They actually work well together. There is not a lot of animosity."

Moss has been meeting monthly with the Paxil plaintiffs lawyers and the Paxil defense team, Sheller said.

* * *

More of the cases that are settling involve cardiac defects, but there are other minor plaintiffs alleging defects because of their mothers' use of Paxil, Sheller said.

189. On July 15, 2010, as also outlined *supra*, GSK issued a press release stating, in part, that it expected to "record a legal charge of $2.36 billion" for, *inter alia*, settlement(s) concerning Paxil.

190. Also on July 15, 2010, *bnet*, the *CBS Interactive Business Network*, published an astute article entitled "In Plain Sight: GSK's Avandia Mess Eclipses Federal Probe of Paxil Factory." The article outlined information regarding the Cidra plant and GSK's manufacture and distribution of Paxil, and stated, in part, that:

> GlaxoSmithKline (GSK) appears to be trying to get all its bad news out at once with its announcement of a $2.36 billion writedown for legal expenses. The charge includes costs for its recent Avandia woes — it settled about 10,000 cases for $460 million — but $750 million of it ends a Department of Justice investigation of its Paxil and Avandamet factory in Cidra, Puerto Rico.
>
> If your reaction to that was, "Wait, what Paxil investigation?" you're not alone. In fact, the feds have been probing GSK's Cidra operations since late 2002, and the Avandia mess conveniently eclipses a scandal about the way Paxil (an antidepressant) and Avandamet (a diabetes drug that uses Avandia as an ingredient) were made. . . .
>
> * * *
>
> What's interesting here is that taken together, there was clearly a huge scandal at its Paxil factory but because information about it dribbled out over a period of eight years it generated very few headlines. GSK's announcement today is a masterpiece of spin: It knows it's trapped in the headlines over the FDA's Avandia review, and it's using that to hide in plain sight what may have been an equally serious issue: The fact that, for years, its Avandamet and Paxil factory made such bad quality medicine that it was busted by the feds and had to be closed.

191. According to a press release issued on August 19, 2010 by the United States Attorney's Office for the Eastern District of Louisiana, Dr. Maria Carmen Palazzo, a GSK researcher, pled guilty to 15 counts of "failing to prepare and maintain records, with intent to

defraud and mislead in connection with clinical trials to evaluate the efficacy and safety of Paxil in children and adolescents with Obsessive-Compulsive Disorder (OCD)." She was sentenced to 13 months in prison to run concurrently with her 87 month sentence resulting from an April 17, 2008 guilty verdict on 39 counts of healthcare fraud unrelated to the Paxil charges.

192. In response to the August 19, 2010 press release regarding Dr. Palazzo, a September 2, 2010 article published by LawyersandSettlements.com reported that:

> GlaxoSmithKline is the subject of more bad publicity after a researcher was allegedly found to have falsified data in trials about Paxil. Meanwhile, the drug maker faces lawsuits alleging newborns suffered Paxil Birth defects when they were exposed to Paxil prior to birth.
>
> The psychiatrist who reportedly falsified clinical data, Dr. Maria Carmen Palazzo, was a clinical investigator on studies conducted by SmithKline Beecham (doing business as GlaxoSmithKline). According to CNBC on 8/20/10, Palazzo has now pleaded guilty to 15 counts of failing to prepare and maintain records with the intent to defraud and mislead.
>
> Palazzo reportedly included children in a study that involved diagnoses the children did not have. Prosecutors claimed that Palazzo also reported symptoms that her study subjects did not exhibit. She was sentenced to 13 months in prison, which she is serving at the same time as an 87-month term for healthcare fraud.
>
> According to BNET (08/19/10), Palazzo was charged after the Federal Drug Administration (FDA) accused her of enrolling children in studies of obsessive-compulsive disorder and major depressive disorder even though the children she studied did not have the proper diagnosis for inclusion in the study.
>
> Paxil now carries a black box warning about the risk of suicide in children. It also carries a warning about the risk of birth defects in babies exposed to the antidepressant prior to birth.
>
> Lawsuits filed against GlaxoSmithKline allege the company did not adequately warn patients about the risk of birth defects, resulting in babies being born with serious health problems, including heart defects and persistent pulmonary hypertension of the newborn (PPHN).

> GlaxoSmithKline reportedly settled a number of Paxil birth defect lawsuits, although the financial terms of the settlement were not disclosed. In announcing the settlement, the drug company said via e-mail that it "has reached agreement to settle certain cases involving the use of Paxil during pregnancy. The details of those settlements are confidential. Other cases remain pending."
>
> It is currently not known how many cases were settled, for what amounts or how many cases are pending. *Bloomberg* reported on 7/20/10 that Paxil agreed to pay more than $1 billion to settle more than 800 lawsuits that alleged Paxil was responsible for birth defects. *Bloomberg* further noted that the settlement works out to approximately $1.2 million to families and leaves around 100 lawsuits pending.

193. In addition to the fact that relevant information was not disclosed to members of the purported Class regarding, *inter alia*, the manufacture of Paxil at the Cidra plant, as outlined *supra*, the GSK Stock Fund was also an imprudent investment for the Plans during the Class Period due to the resolution of litigation, particularly through a substantial number of Class Period settlements, concerning to Paxil and, *inter alia*, users withdrawal problems, birth defects, and increased suicidal tendencies.

FACTS CONCERNING AVANDIA

194. One of the drugs developed and manufactured by GSK was Avandia, generically referred to as rosiglitazone, which was marketed by GSK as a drug intended to help improve blood sugar control in type 2 diabetics. Type 2 diabetes is a life threatening disease that, according to the FDA, as of June 2007, affected approximately 18 to 20 million Americans.

195. In 1999, Avandia was approved by the FDA for the treatment of type 2 diabetes.

196. From 1999 through 2006, GSK sold more than $12 billion worth of Avandia.

197. In April 2002, Avandia's label received warnings about an increased risk of heart failure.

198. In September 2005, GSK completed the first of two meta-analyses[4] it performed in connection with Avandia. Specifically, GSK conducted a patient-level meta-analysis of safety data from 37 clinical trials (the "First Meta-Analysis"). GSK's First Meta-Analysis demonstrated an estimate of excess risk of ischemic cardiovascular events (*i.e.*, an increased risk of heart attack, associated with the use of Avandia). GSK did not, however, publicize that the results of its First Meta-Analysis showed an increased risk of heart attacks associated with the use of Avandia.

199. In January 2006, GSK conducted a second meta-analysis of Avandia (the "Second Meta-Analysis"). The Second Meta-Analysis was performed in order to incorporate five additional studies that had been completed between September 2004 and August 2005 (for a combined total of 42 clinical trials). The results of GSK's Second Meta-Analysis were finalized in March 2006. GSK's Second Meta-Analysis showed an estimate of excess risk of ischemic cardiovascular events associated with the use of Avandia that was even greater than the risk portrayed in the First Meta-Analysis.

200. The increased risk of ischemic cardiovascular events presented by the Second Meta-Analysis was statistically significant. GSK did not, however, publicize that the results of its Second Meta-Analysis showed a risk of heart attacks associated with the use of Avandia that was statistically significant.

201. According to the FDA, in August 2006, GSK provided the FDA with a pooled analysis (meta-analysis) of 42 separate, double-blinded, randomized, controlled clinical trials to assess the efficacy of Avandia for treatment of type 2 diabetes, compared to either placebo or

[4] A meta-analysis is known as the synthesis of research results through the use of an array of statistical methods to cull and merge results from previously performed separate, but related, studies. This type of analysis is done when the individual studies, alone, would not be deemed large enough to adequately examine a particular question.

other anti-diabetic therapies in patients with type 2 diabetes. According to the FDA, it did not publicly discuss the data submitted by GSK at the time it was submitted in August 2006 because the FDA wanted to wait until it was able to perform a comprehensive internal re-analysis of that data.

202. In a March 2007 Dimensions Newsletter issued to GSK U.S. employees and edited by GSK employees, Defendants touted the Avandia range of the products, stating, in part that:

> The *Avandia* range of products for diabetes continue to perform strongly, with overall sales of £1,645 million (+25%). Data from the landmark ADOPT and DREAM studies are expected to be filed with regulatory agencies in the first half of 2007. Respectively, the studies demonstrated that *Avandia* is more effective that metformin in long-term blood sugar control in type 2 diabetes and that *Avandia* reduced the risk of progression to type 2 diabetes.

203. In that same newsletter, Defendants also stated that with regards to U.S. Pharmaceuticals, "[t]otal turnover grew by 16% driven by," *inter alia*, Avandia sales (+24%).

204. The March 2007 Dimensions Newsletter also provided Participants who were U.S. employees a full-page article entitled "Prevention, intervention and innovation[:] *Avandia* Helping those with type 2 diabetes." Among other things, the article stated that:

> This disease is also associated with an increased risk for a number of serious, sometimes life-threatening complications.
>
> These complications can result in increased healthcare costs and decrease a person's quality of life. But for those who suffer from 2 diabetes, *Avandia* has helped many of them control elevated blood glucose levels that characterize this disease.

205. That issue of the newsletter also stated:

> The ADOPT study (A Diabetes Outcome Progression Trial), funded by GSK, involved 4,360 patients with type 2 diabetes at more than 400 sites throughout North America and Europe. Results from the landmark trial, published in *The New England*

> *Journal of Medicine*, demonstrated that initial treatment with rosiglitazone can help sustain glycemic control over time.

206. On May 21, 2007, the FDA issued a safety alert addressing the potential risks identified by its own pooled analysis of completed controlled clinical trials. The analysis showed an increase in the risk of heart attack and heart-related deaths in patients taking Avandia. According to the FDA's initial analysis of GSK's meta-analyses, the data from GSK's analyses expressed a significant concern with respect to the excess risk of myocardial ischemic events (*e.g.*, heart attacks) in patients taking Avandia.

207. That same day, another meta-analysis of rosiglitazone (Avandia) studies, conducted by Dr. Stephen Nissen (the "Nissen Study"), was published in *The New England Journal of Medicine* ("*NEJM*"). Dr. Nissen concluded that patients taking Avandia were at an increased risk for heart attacks.

208. Dr. Nissen's analysis was based on data derived from 42 controlled clinical trials. According to published reports and FDA statements, many – but not all – of the 42 controlled clinical trials utilized by Dr. Nissen were the same studies used by GSK in its meta-analyses.

209. Following the publication of the Nissen Study findings on May 21, 2007 and the FDA's safety alert, the price of GSK ADSs dropped considerably.

210. The FDA, in or around the same time period, stated that it was not aware of Dr. Nissen's study methods or findings until the date of his study's publication in the *NEJM*.

211. However, GSK was in possession of the Nissen Study, according to the Senate Report, defined *infra*. Yet, despite the fact that the Company was well aware of Dr. Nissen's findings and that its head of research and Defendant herein, Moncef Slaoui, agreed with the conclusions of the Nissen Study, Defendants refuted its findings. Instead, GSK embarked on a systematic attack of the Nissen Study, alleging that it was unsound. Worse, as outlined in the

Senate Report, Defendants began to intimidate scientists and suppress information to protect the Company's Avandia sales.

212. An August 2010 *Time Magazine* article verified the time-table, reporting the following:

> Five days before a 2007 article in the *New England Journal of Medicine* showed that the diabetes drug Avandia was linked to a 43% increase in heart attacks compared with other medications or placebos, a group of scientists and executives from the drug's maker, GlaxoSmithKline (GSK), gathered in a conference room at the offices of the Food and Drug Administration in White Oak, Md. The GSK goal: to convince regulators that the evidence that the company's $3 billion-a-year blockbuster drug caused heart problems was inconclusive. To do that, the GSK officials focused not on heart-attack data but on a broader, less well defined category of heart problems called myocardial ischemia. The most recent studies of Avandia, the GSK officials told the FDA, had "yielded information that is inconsistent with an increased risk of myocardial ischemic events," according to sealed court proceedings obtained by TIME.
>
> What GSK didn't tell the FDA was that on May 14, 2007, two days before the White Oak meeting, GSK's Global Safety Board had noted that a new assessment of Avandia studies "strengthens the [cardiac-risk] signal observed in the [previous] analysis." Or that eight days earlier, the company's head of research and development, Moncef Slaoui, had sent an e-mail to its chief medical officer saying Avandia patients showed an "increased risk of ischemic event ranging from 30% to 43%!" Or that the day before the meeting, the company had produced a preliminary draft report that showed patients on Avandia had a 46% greater likelihood of heart attack than those in a control group.
>
> But the mixed-evidence argument GSK presented to the FDA worked. After months of deliberation, the agency decided to keep the drug on the market — a move worth billions of dollars to GSK but that also may have put millions of patients at risk.

213. On May 31, 2007, an article in *The Wall Street Journal* reported that in a letter published on the website of *The Lancet*, a leading medical journal, GSK's Chief Medical Officer, Ronald Krall, wrote and acknowledged that the Company had found indications of increased risk

of heart attacks associated with Avandia in its own previously conducted meta-analyses of clinical studies of Avandia.

214. On July 9, 2007, in an article in *The Wall Street Journal* concerning GSK and Avandia, Defendant Garnier admitted that GSK had performed its own meta-analyses and found that Avandia caused an increased risk of heart attack. According to the same article, Defendant Garnier also conceded that GSK had failed to adequately communicate the risks of Avandia.

215. In July 2007, an FDA advisory committee, in a 20-3 vote, agreed that Avandia was tied to increased ischemic risk, meaning an increased risk for heart attacks. At the time it was also widely-reported that the FDA would require GSK to add a "black box" warning to Avandia concerning the risk of heart attacks associated with the drug. Later, according to an October 24, 2007 article in *The Wall Street Journal*, "a black box warning would still represent something of a middle ground in the debate over Avandia," when the alternative could be the outright removal of the drug from the market.

216. On October 2, 2007, the FDA's Drug Safety Oversight Board voted, albeit by a very marrow 8-7 margin, to keep Avandia on the market.

217. On November 14, 2007, the FDA added a "black box" warning to the label of Avandia. The warning was prompted by the *NEJM*'s analysis, as well as statements referring to three studies that the FDA stated "have not confirmed or excluded" whether the drug increases its users' risk for heart attack, and that the available data is "inconclusive."

218. On February 20, 2010, the United States Senate Committee on Finance (the "Finance Committee") issued a press release, entitled "Baucus, Grassley Release Finance Committee Report on Diabetes Drug Avandia, Express Concern About FDA's Role in Protecting Patients in Ongoing Avandia Study" (the "Senate Finance Committee Press Release"),

concerning the release of the Finance Committee's "Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia" (the "Senate Report"). The Senate Report was based on an exhaustive two-year inquiry of Avandia.[5]

219. The Senate Report confirmed that GSK knew, prior to the May 21, 2007 *NEJM* article, that there were cardiac risks associated with Avandia, and, despite knowing those risks, the Company did not publicize information regarding, or warn of, Avandia's cardiac risks.

220. The Senate Report provided a chronology of Avandia-related events and issues that encompassed the following:

> **2004 –**
>
> A GSK sponsored trial (the "RECORD trial"[6]) is known to be statistically inadequate to answer questions on cardiovascular safety. GSK created studies to counter Takeda Pharmaceutical's PROactive[7] study on ACTOS,[8] a competitor to Avandia. Finance Committee investigators also learned that GSK was aware, since at

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[5] The Finance Committee investigators reportedly reviewed over 250,000 pages of documents provided by GSK, the FDA, the University of North Carolina and others. The Finance Committee investigators also conducted numerous interviews and phone calls with GSK, the FDA, and anonymous whistleblowers. GSK produced data concerning the RECORD (defined in footnote 6) study, including emails, GSK slide presentation(s) and other documents created in 2004 to 2006.

[6] The RECORD (Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes) trial is a large, prospective, randomized, controlled study that was initiated in 2001, and designed to compare cardiovascular outcomes of patients on Avandia. The RECORD trial was a GSK sponsored trial of Avandia.

[7] The PROactive (PROspective pioglitAzone Clinical Trial In macroVascular Events) study involved 5,238 patients in 19 European countries who had experienced one or more cardiovascular events such as a heart attack, coronary artery bypass surgery or stroke. The PROactive study demonstrated that pioglitazone significantly reduces the risk of heart attacks, strokes and death in high risk patients with type 2 diabetes. The study was commissioned by Takeda Pharmaceuticals.

[8] ACTOS (pioglitazone) – once-a-day prescription medication for type 2 diabetes that helps the body control blood sugar (glucose) levels. ACTOS is produced by Takeda Pharmaceuticals and is Avandia's primary competitor.

least 2004, that the RECORD trial was statistically inadequate, or "underpowered," to answer questions regarding cardiovascular safety. According to internal GSK material, such "inconclusive" results favored GSK and the marketing strategy for Avandia. Further, experts were advising GSK, since approximately 2004, about the possible biological mechanisms related to why Avandia may cause an increased risk for heart attacks.

2004 -

GSK experts advise the Company as to the possible biological mechanisms behind the cardiovascular risk associated with Avandia.

September 2004 -

GSK commissions an observational study to examine over 11,000 subjects for an "initial" analysis of the link(s) between Avandia and myocardial ischemia. The study included 11,586 subjects randomly placed in clinical trials before September 20, 2004. The analysis of the trials was completed during the Fall of 2005 and showed a hazard ratio for myocardial ischemia of 1.29; meaning, the rosiglitazone increased the risk of heart-related ischemia by 29 percent. This number was considered statistically significant.

June 3, 2004 -

GSK's clinical manager reports on feedback from a consultant who expressed concern over the cardiovascular risks of Avandia. In June 2004, GSK's leader for a cardiac safety study entitled the "Avandia 211 Cardiac Heart Failure Study," (the "Avandia 211 Study") reported on a meeting with a consulting academic. And, the report showed increased cardiovascular ("CV") mortality and morbidity data, with increased CV events, hospitalizations, and ischaemic events.

December 2, 2004 -

Internal GSK material highlight the inadequacy of the RECORD trial. RECORD was shown to have "low events rates," meaning that the study did not have the statistical "power" to give sufficient cardiovascular event data. The document also stated, "PROactive results to be coming soon—need to be able to respond to a variety of different outcomes. Communications plan in place for various possible outcomes of PROactive."

June 2005 -

A briefing document on GSK's cardiovascular plan for Avandia notes several "important limitations of RECORD," including the study release date and the low event rate. The study release date was 2009, and the observed rate for the primary endpoint was approximately 3.5 percent per annum, which is much lower than that anticipated in the original [-- protocol. 11 percent per annum--].

July 18, 2005 -

GSK holds a meeting to discuss the need for a study to compete with PROactive to, in particular, address the "European commercial need" for a study. GSK officials continued, internally, to express concern about cardiovascular problems associated with Avandia. GSK held a meeting on July 18, 2005 to discuss the need for a study to compete with PROactive which indicated positive findings for ACTOS -- an inherent negative to Avandia and its sales. The briefing document from this meeting discussed the ''European Commercial Need'' for a study:

> A recently completed evidence gap analysis completed by the Metabolic Centre of Excellence has identified the need for the rapid generation of clinical endpoint data to support the superiority of rosiglitazone [Avandia] for the prevention of future cardiovascular clinical events in patients with [type 2 diabetes mellitus]. Publication of the PROactive data may result in important commercial disadvantage in Europe. We therefore have the opportunity to start a CV outcomes study with the aim of getting superiority data in 2007.

The document also noted that GSK's studies provided insufficient data on cardiovascular outcomes:

> The primary endpoint in RECORD is powered for noninferiority and taking into account the low observed event rate, it is unlikely that this study will demonstrate any potential for [Avandia] combination to be superior in terms of the primary endpoint compared to SU+MET combination therapy. DREAM[9] and ADOPT[10] are

[9] The DREAM (Diabetes Reduction Assessment with ramipril and rosiglitazone Medication) trial evaluated the likelihood of progression to type 2 diabetes among participants with a condition known as "pre-diabetes." The DREAM trial found that ramipril did not alter the cardiorenal outcome or its components. Rosiglitazone, which reduced diabetes, also reduced the development of renal disease but not the cardiorenal outcome and increased the risk of heart failure.

> collecting CV safety data, but these are low risk populations and it is unlikely that [Avandia] will be superior to controls for the prevention of CV events.

Fall 2005 -

GSK presents an observational trial of Avandia. The first study included 11,586 subjects randomly placed in clinical trials before September 20, 2004. The analysis of the trials was completed during the fall of 2005 and provides a hazard ratio for myocardial ischemia of 1.29; meaning that Avandia increased the risk of heart-related ischemia by 29 percent. GSK's second observational study involved analyzing 14,237 patients by the summer of 2006 and found a hazard ratio of 1.31; meaning that Avandia increased the risk of myocardial ischemia by 31 percent.

Late 2005 -

GSK prepares an analysis addressing the underlying cause for the increase in ischemia to Avandia-prescribed patients and summarizes the cardiovascular events in Avandia clinical trials discussing the underlying cause for the increase in myocardial ischemia by users of Avandia.

Early 2006 -

GSK insiders acknowledge that the ADOPT and DREAM studies indicate a signal for heart failure and ischemic events. According to GSK interal documents, GSK's experts were discussing these problems as early as 2006.

Summer 2006 -

The results of the GSK ''updated'' trial were presented. The results showed that the hazard ratio of these results was 1.31; meaning that Avandia increases the risk of myocardial ischemia by 31 percent.

May 2, 2007 -

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[10] ADOPT (A Diabetes Outcome Progression Trial) was a clinical trial designed to evaluate, in patients recently diagnosed with type 2 diabetes, the long-term efficacy of monotherapy with rosiglitazone on glycemic control and on the progression of pathophysiological abnormalities associated with type 2 diabetes as compared with metformin or glyburide monotherapy. ADOPT demonstrated that initial treatment with Avandia reduced the risk of monotherapy failure in people with type 2 diabetes by 32% compared to metformin, and 63% compared to glyburide at five years.

Dr. Nissen submits his meta-analysis on Avandia to the *NEJM* for peer review and publication. *NEJM* then sent confidential copies of the study to several independent experts, including Dr. Steve Haffner, an *NEJM* peer reviewer and consultant for GSK, to peer review Dr. Nissen's study.

May 3, 2007 -

Dr. Haffner leaks Dr. Nissen's study draft on Avandia to GSK. GSK produces a detailed analysis of Dr. Nissen's paper -- weeks before the *NEJM* public release. GSK, in an attempt to find deficiencies in Nissen's meta-analysis, noted: "The selection of trials therefore appears to be thorough."

GSK also performed a regression analysis on each study that Dr. Nissen used in his meta-analysis to ascertain whether the effects of myocardial infarction and/or cardiovascular death would still appear. The analysis was statistically similar to Dr. Nissen's findings and, as a result, GSK could not establish a basis for disregarding the findings as presented.

May 8, 2007 -

Moncef Slaoui, head of research for GSK, writes an email to several executives agreeing with the conclusions found in Dr. Nissen's article. Commenting on the meta-analyses, Dr. Slaoui wrote:

> FDA, [Dr.] Nissen and GSK all come to comparable conclusions regarding increased risk for ischemic events, ranging from 30 percent to 43 percent!
>
> FDA and [Dr.] Nissen (but no final data from GSK [to] date) reach the conclusion of an [hazard ratio] for death (CHF + IHD) of 1.72 or 1.75!

May 9, 2007 -

Sir Colin Dollery, a senior consultant to GSK, laid out many of the problems with Avandia in an email to Dr. Slaoui and others. Mr. Dollery wrote as follows: "To a great extent, the numbers are the numbers, the [Dr. Nissen] analysis is very similar to our own. . . . We cannot undermine the numbers but I think they can be explained so we must concentrate on effective risk management." Sir Dollery further noted that the PROactive study on ACTOS (pioglitazone) undermined the effectiveness of Avandia (rosiglitazone), and Avandia's ability to avoid ischemic events.

May 21, 2007 -

NEJM publishes Dr. Nissen's meta-analysis and, that same day, GSK responds with the following defensive statement:

> "GSK strongly disagrees with the conclusions reached in the *NEJM* article, which are based on incomplete evidence and a methodology that the author admits has significant limitations." Instead, GSK highlighted the results of Company sponsored trials like RECORD as "the most scientifically rigorous way to examine the safety and benefits of a medicine."

May 23, 2007 -

A GSK official emails members of the RECORD steering committee requesting a meeting to discuss the publication of the RECORD study's interim results. Internal e-mails show that GSK executives were intent on publishing the interim results, regardless of their results, in an effort to favor GSK and its Avandia sales.

May 29, 2007 -

RECORD interim results were submitted to *NEJM* for peer review and publication. An author of the RECORD, despite attempting to disassociate Avandia with myocardial infarctions, acknowledged that there is a tendency supporting Dr. Nissen's argument.

June 1, 2007 -

Peer reviewers criticize the RECORD authors' attempts to temper to the ill-effects of Avandia, observing that, ultimately, their findings are completely compatible with the results of the meta-analysis by Dr. Nissen.

June 6, 2007 -

The House of Representatives Committee on Oversight and Government Reform held a hearing concerning Avandia and its side-effects.

221. According to the Senate Report, the Finance Committee began its investigation in May 2007 after the *NEJM* published the Nissen Study. During its investigation, the Finance Committee determined that evidence demonstrated that GSK knew, or should have known, for several years prior to the *NEJM* article, that there were possible cardiac risks associated with

Avandia. And, despite the fact that at least one Company insider and Defendant herein agreed with the findings of the Nissen Study, the Company chose to not disclose any information regarding Avandia's cardiac risks.

222. Instead, according to the Senate Report:

> When an independent scientist [Dr. Nissen] sought to publish a study in 2007 pointing out the cardiovascular risk of Avandia, GSK acquired a leaked copy of that study from one of its consultants prior to the study being published. The company's own experts analyzed the study, found it to be statistically reliable, and then attacked the soundness of that study in press releases and public comments. GSK also sought to counter the study's findings by quickly releasing preliminary results from its own study on Avandia, even though the company's internal communications established its study was no primarily designed to answer questions about cardiovascular risk.

223. What is more, there appears to be a questionable relationship, and perhaps a conflict of interest, between GSK and the FDA with respect to the approval of Avandia. According to a June 12, 2007 *USA Today* article entitled "FDA scientist says she was reprimanded for warning," when Dr. Rosemary Johann-Liang, former deputy director of the FDA's Division of Drug Risk Evaluation, took her staff's advice to recommend that Avandia get the "black box" warning about congestive heart failure, she was also "verbally reprimanded and told to talk to her director before making any major recommendations related to drug safety." While the title of the article states that Dr. Johann-Liang claimed she was reprimanded for the warning, the body of the article actually states that "FDA staffers told Senate Finance Committee investigators" about the reprimand. Accordingly, after Dr. Johann-Liang voluntarily left the FDA for another job, she stated that: "[S]he might have tried to figure out how to stay at the FDA 'if the agency had a vision of promoting and protecting public health.'"

224. According to Senator Max Baucus, in the Senate Finance Committee Press Release, "Americans have a right to know there are serious health risks associated with Avandia and [GSK] had a responsibility to tell them." *See* Finance Committee Press Release.

225. Similarly, Plan Participants had a right to have the Company only allow Plan investment in GSK ADSs if the stock was prudent; however, because of the unknown serious health risks associated with Avandia, and the associated harm to the Company overall, the ADSs were not prudent.

226. On July 13 and 14, 2010, an FDA advisory committee met to review Avandia and its risk for heart attack for users and vote on whether to pull Avandia off the market. Twelve of 25 panelists voted to pull Avandia off the market. Ten others voted to keep Avandia on the market, albeit with greatly restricted use. Three minority panelists voted for the drug to remain on the market without newly-issued restrictions.

227. On July 15, 2010, as also outlined *supra*, GSK issued a press release stating, in part, that it expected to "record a legal charge of $2.36 billion" for, *inter alia*, settlement(s) concerning Avandia.

228. According to a July 19, 2010 article in *USA Today*, entitled "Doctors say it's already over for diabetes drug Avandia," Dr. Clifford Rosen, a senior endocrinologist with the Maine Medical Center Research Institute – and one of the ten FDA advisory panel members who voted to keep Avandia on the market – stated he would actually prefer if the FDA withdrew the drug. According to the article, Dr. Rosen did not vote to pull Avandia off the market at the July 13 and 14, 2010 meetings because he was "very anxious" he would be the only one. Dr. Rosen further stated that he believed "the drug is done. Nobody should be prescribing it. Anybody who went to or heard this meeting would never prescribe [Avandia] under any circumstances."

Dr. Rosen previously chaired the 2007 FDA advisory committee and stated, in the *USA Today* article, that he has not prescribed Avandia since that 2007 advisory committee meeting.

229. On July 21, 2010, the Company issued a press release concerning its second quarter 2010 financial results. The Company reported a £1.9 billion decline in U.S. sales, admittedly attributable to lower Avandia sales. According to a *Reuters* report that same day, "earnings slumped 92 percent" during the second quarter.

230. Additionally, on July 21, 2010, the FDA ordered GSK to discontinue new patient enrollment for the post-marketing TIDE[11] trial of Avandia and to update those involved in the TIDE trial – investigators, institutional review boards and ethics committees – regarding the new safety information presented at the joint FDA advisory committee meetings held on July 13 and 14, 2010.

231. That same day, a *Reuters* article stated that prior to the 2007 study linking Avandia to a greater risk of heart attacks, the drug was GSK's "second biggest drug at $3 billion a year."

232. During this time, GSK became a target of numerous lawsuits pertaining to the use of Avandia. According to a July 13, 2010 *Bloomberg* report, GSK agreed to pay approximately $460 million to settle a substantial portion of Avandia-related lawsuits. And, on July 15, 2010, the Company announced that it expected to record a $2.36 billion charge for the second quarter of 2010 for legal costs.

[11] The TIDE (Thiazolidinedione Intervention With Vitamin D Evaluation) trial was initiated in 2007 to examine the comparative cardiovascular safety of rosiglitazone (Avandia) and pioglitazone (ACTOS, Takeda) in patients with type 2 diabetes. The trial was mandated by the FDA.

233. In August 2010, *Cardiology News* reported that Avandia "***accounted for 1,354 patient deaths in 2009, more than any other prescription drug,***" according to a June report from the Institute for Safe Medication Practices. (Emphasis added).

234. Also, in or around August 3, 2010, a new study to be published in the October 2010 issue of the *Journal of Clinical Endocrinology & Metabolism* suggested that Avandia increased the risk for fractures in postmenopausal women and in men taking both loop diuretics and thiazolidinediones.

235. In response to *Time Magazine*'s article stating that GSK withheld information from the FDA (discussed above), the FDA commenced an investigation as to whether GSK broke the law by failing to fully inform the FDA about the heart risks linked to Avandia.

236. On August 19, 2010, *The New York Times* reported, in an article entitled "Glaxo Memo on Avandia Is Questioned," that the FDA had required GSK to send a letter to crucial doctors describing the FDA hearings in July 2010 concerning Avandia and the TIDE trial. The article further reported that the FDA regulators found the Company's letter misleading and that it could endanger patients.

237. According to another *The New York Times* article published the next day, entitled "Glaxo Account of Hearing Questioned":

> [A] federal official and some members of the panel now say the company's letter is misleading and could endanger patients. The dispute is occurring just weeks before the Food and Drug Administration is expected to announce whether Avandia's label must include new warnings, whether sales of the drug will be restricted or whether Avandia must be withdrawn from the market.
>
> Doctors who received the letter, dated July 28, are investigators in a study called the Tide trial, which was intended to compare the heart risks of Avandia with those of Actos, a similar drug made by Takeda Pharmaceuticals.

Results of the trial, which was requested by the F.D.A., are not expected for years. The ethics of the Tide trial were a point of contention at the advisory committee hearing, and the F.D.A. ordered GlaxoSmithKline to stop recruiting new patients into the trial, although current patients could continue.

Dr. David Graham, an F.D.A. medical officer, made an impassioned presentation at the advisory hearing arguing that the study should be stopped because thousands of patients in the trial were being exploited. None of these arguments were mentioned in GlaxoSmithKline's letter.

"This summary is biased, misleading and not truthful," Dr. Graham said in an interview. "The whole purpose of this letter is so that they can reassess whether this is an ethical trial going forward, but the step-by-step ethical flaws and problems with the Tide trial are not even referenced."

Several members of the advisory committee complained that the company's letter was biased.

"This letter is really deceptive," said Dr. Clifford J. Rosen, a panel member. He added that the letter also did not refer to a presentation at the hearing by members of an Institute of Medicine study panel that said observational studies could be useful.

Dr. Curt D. Furberg, also a panel member, described the letter as a "very Avandia friendly" document that ignored much of the discussion criticizing the validity of GlaxoSmithKline's studies. Other panel members expressed similar reservations.

But another panel member, Dr. Sanjay Kaul, disagreed, saying the letter "faithfully reflects the deliberations of the Avandia advisory meeting."

Erica Jefferson, an F.D.A. spokeswoman, said that after ordering GlaxoSmithKline to send a summary of the hearing to the Tide trial investigators, the agency had relied on the company to provide a balanced account. "F.D.A. did not preclear or approve the content," she said.

Mary Anne Rhyne, a GlaxoSmithKline spokeswoman, said the company had only one week to write the 10-page summary, which was necessarily brief. But the company and the leader of the Tide trial agreed that the letter "reflected the science and data discussed at the advisory committee meeting," Ms. Rhyne said.

> Dr. Steven Nissen, a Cleveland Clinic cardiologist who made a presentation before the committee arguing for Avandia's withdrawal, said that GlaxoSmithKline's letter did not mention that the committee had concluded that Avandia carried a higher risk of heart attack than Actos.
>
> "Since the Tide trial compares these two alternative therapies, ***this omission does not meet any reasonable ethical standards***," Dr. Nissen said.

(Emphasis added).

238. On September 1, 2010, Gerald Dal Pan, M.D., Director of the Office of Surveillance and Epidemiology office of the FDA, addressed a study comparing cardiovascular and mortality risks in elderly Medicare patients initiating therapy with a thiazolidinedione in which use of rosiglitazone (Avandia) was compared with pioglitazone. The study had found that rosiglitazone (Avandia) increased the risk of hospitalized stroke, hospitalized heart failure, all-cause mortality and the composite end points of acute myocardial infarction or death.

239. On September 22, 2010, Janet Woodcock, M.D., Director for the Center for Drug Evaluation of the FDA, issued a memorandum summarizing her decision on the continued marketing of rosiglitazone (Avandia included). Dr. Woodcock determined that rosiglitazone may be permitted to remain on the market ***provided that*** GSK performs the following actions:

> 1. GSK is directed to undertake a restricted access program under a Risk Evaluation and Mitigation Strategy ("REMS") with elements to assure safe use, including:
>
> > (a) Provision of complete risk information to each patient and documentation in their medical record that the information has been received and understood;
> >
> > (b) Documentation from health care providers that each patient receiving rosiglitazone falls into one of two categories:
> >
> > > (i) patients currently taking rosiglitazone, or

> (ii) patients not already taking rosiglitazone who are unable to achieve glycemic control on other medications and, in consultation with their health care professional, decide not to take pioglitazone for medical reasons;
>
> (c) Documentation from health care providers that the risk information has been shared with each patient; and
>
> (d) Physician, patient, and pharmacist enrollment.
>
> 2. GSK is required to commission an independent re-adjudication of the RECORD study. This could be conducted in a stepwise manner with initial examination of the mortality finding; if the mortality finding is determined to be valid, then the other MACE[12] elements should be re-adjudicated. Considering the time and effort spent by the thousands of volunteers who participated in RECORD, I believe every effort should be made to learn as much as possible from its results.
>
> 3. The TIDE trial is placed on full clinical hold and the regulatory deadlines for its conduct are rescinded. If reliable information on ischemic risk can be obtained from the re-adjudication of RECORD, the benefit-risk information for rosiglitazone should be re-evaluated and the conduct of further safety studies (including studies versus pioglitazone) re-considered.

Thus, the FDA's decision will allow patients in the United States access to Avandia only if they and their doctors attest that they have tried every other diabetes medicine and that patients have been apprised of the drug's substantial heart risks.

240. The reasoning supporting Dr. Woodcock's decision stems from "multiple signals of concern." Dr. Woodcock stated that available evidence does not reveal a signal of cardiovascular ischemic risk with pioglitazone, the other (non-Avandia) thiazolidinedione-class drug available on the U.S. market. Based on this safety information, Dr. Woodcock concluded that it was necessary to restrict access to rosiglitazone (Avandia) until more substantial evidence

[12] MACE is a combined measure of nonfatal myocardial infarction, nonfatal stroke, and CV death.

of its safety becomes available. Dr. Woodcock explained that she terminated the TIDE trial because of the restrictions she determined were necessary for rosiglitazone and the level of concern about its cardiovascular safety. In conclusion, Dr. Woodcock stated, in pertinent part, as follows:

> In summary, there are multiple and conflicting signals of cardiovascular ischemic risk related to rosiglitazone. ***The current cardiovascular safety database for rosiglitazone does not provide an assurance of safety at the level set out in FDA's guidance for marketed anti-diabetic drugs.*** There are not similar signals pertaining to the only other drug in the TZD class available in the US, pioglitazone. Marketing of rosiglitazone will be restricted and the sponsor will be required to commission an independent verification of the RECORD data.

(Emphasis added).

241. On September 23, 2010, the FDA held a conference call concerning Advania and announced that it will significantly restrict the use of Avandia according to Dr. Woodcock's decision. Dr. Margaret Hamberg, FDA Commissioner, announced, in pertinent part, the following:

> FDA is significantly restricting the use of these products by requiring the drug sponsor to submit a Risk Evaluation and Mitigation Strategy or REMS. Under the Food and Drug Administration Amendments Act of 2007, FDA can require a drug sponsor to issue a REMS to impose certain restrictions so that the benefit of the drug can continue to outweigh its risks.
>
> Under the REMS for rosiglitazone, the drug will be available to patients not already taking it only if they are unable to achieve glycemic control on other medications and, in consultation with their health care professional, decide not to take pioglitazone for medical reasons. Pioglitazone is the other drug in this class of diabetes medications.
>
> Current users of rosiglitazone will be able to continue using the medication if they appear to be benefiting from it and they acknowledge that they understand these risks. Doctors will have to attest to and document their patients' eligibility.

> Patients will have to review statements describing the cardiovascular safety concerns. The agency anticipates that the REMS will limit use of rosiglitazone significantly. FDA's taking this action after careful consideration of the risks and benefits of rosiglitazone.
>
> Today FDA is also directing the Avandia (or rosiglitazone) sponsor, Glaxo Smith Kline, to conduct an independent review of the results of its large scale clinical trial of Avandia called RECORD. We believe this review may provide additional clarity about this trial and the safety of rosiglitazone.
>
> FDA is also stopping the trial known as TIDE, a comparison study between Avandia and Actos. FDA reached the conclusion that this study does not meet the criteria recommended by an Institute of Medicine committee for safety studies at this time.

242. In addition, Dr. Hamburg reported that there are about 600,000 people taking Avandia (at or around the September 2010 time period) in the United States and that she believed "the numbers will go down very, very significantly with these new requirements."

243. Further, on September 23, 2010, the European Medicines Agency ("EMA,")[13] an agency of the European Union that is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union, recommended suspension of Avandia. Medicines with rosiglitazone will stop being available in Europe within the next few months. The EMA released the following directive concerning the withdrawal of rosiglitazone:

> Doctors should stop prescribing rosiglitazone-containing medicines. Patients taking rosiglitazone-containing medicines should be reviewed in a timely manner to amend their treatment.

[13] The 27 voting members of the EMA are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom. In addition, Norway, Iceland and Liechtenstein, which are non-voting members of the EMA, are also affected.

> The current review of rosiglitazone by the Agency's Committee for Medicinal Products for Human Use (CHMP) was initiated on 9 July 2010 following the availability of new studies questioning the cardiovascular safety of the medicine.
>
> ***Since its first authorisation, rosiglitazone has been recognised to be associated with fluid retention and increased risk of heart failure and its cardiovascular safety has always been kept under close review.*** Consequently, the use of rosiglitazone was restricted to a second-line treatment and contra-indicated in patients with heart failure or a history of heart failure when it was first granted a marketing authorisation as Avandia in 2000.
>
> ***Data from clinical trials, observational studies and meta-analyses of existing studies that have become available over the last three years have suggested a possibly increased risk of ischaemic heart disease associated with the use of rosiglitazone.*** Further restrictions on the use of these medicines in patients with ischaemic heart disease were introduced.
>
> ***The availability of recent studies has added to the knowledge about rosiglitazone and overall, the accumulated data support an increased cardiovascular risk of rosiglitazone. In view of the restrictions already in place on the use of rosiglitazone, the Committee could not identify additional measures that would reduce the cardiovascular risk. The Committee therefore concluded that the benefits of rosiglitazone no longer outweigh its risks and recommended the suspension of the marketing authorisation of the medicines.***
>
> The suspension will remain in place unless the marketing authorisation holder can provide convincing data to identify a group of patients in whom the benefits of the medicines outweigh their risks.
>
> The Committee's recommendation has now been forwarded to the European Commission for the adoption of a legally binding decision.

(Emphasis added).

244. Thereafter, sales of Avandia were suspended entirely in Europe, while patients in the United States are allowed restricted access.

245. According to an article in *The New York Times*, dated September 24, 2010, Dr. Nissen said that the FDA's decision brought an end to "one of the worst drug safety tragedies in our lifetime," adding that it was "essential to fully investigate what went wrong with the regulatory process to prevent this type of tragedy from endangering patients in the future." In deciding not to solely add more warnings to the label to address the risk of Avandia, Dr. Woodcock stated: "We know that labels are often not read."

246. In response to the FDA and EMA's decisions, the Company issued a press release announcing that the Company will cease promotion of Avandia in all countries in which it operates and will continue to respond to requests for information and support from healthcare professionals and patients. Commenting on the regulatory decisions, Dr. Ellen Strahlman, GSK's Chief Medical Officer, stated, in pertinent part, as follows:

> Our primary concern continues to be patients with type 2 diabetes and we are making every effort to ensure that physicians in Europe and the US have all the information they need to help them understand how these regulatory decisions affect them and their patients.

247. On October 1, 2010, *Global Insight* reported that Brazilian drug regulator Anvisa cancelled the registration of Avandia. Anvisa's decision was based on "studies that suggest that the risks surpass the benefits of the treatment." The article reported that a Colombian drug regulator, The National Institute of Food and Drug Vigilance, known as Invima, also requested the withdrawal of all products containing rosiglitazone. Colombia and Brazil joined other Latin American countries, as well as other nations, on a worldwide basis. The article reported that Mexico and Argentina have introduced restrictions or have cancelled the registration of rosiglitazone in recent weeks.

248. In an article in the October 2010 issue of *Clinical Endocrinology News*, experts responded to the FDA's announcement of the restriction of Avandia. Endocrinologist Dr. Rosen

commented: "This effectively puts an end to rosiglitazone in the United States. . . . It will be very, very rare to have a patient on rosiglitazone." Commenting further on the FDA's decision in an interview, Dr. Rosen stated, in pertinent part, as follows:

> [It] basically puts an end to rosiglitazone prescriptions in the United States. It's almost impossible for an individual practitioner to write a prescription after spending 20 minutes talking about risk, having the patient sign an informed consent, and then filling out forms to send to the FDA. It's just not going to happen.

249. On October 8, 2010, *The Press Trust* of India reported that the government of India banned the production (and import) of Avandia following the U.S. and European Union's restriction and suspension of the drug following reports of its cardiac-causing and related problems. The decision was made at a meeting of a special committee formed to examine whether there was a need to ban Avandia. The special committee was formed by the Drug Technical Advisory Committee of India.

250. An October 21, 2010, press release further revealed that the Company and its subsidiaries were "in the process of responding to a US Department of Justice (DOJ) subpoena" and "Civil Investigative Demands from a number of States Attorneys General offices" all "relating to the development and marketing of Avandia."

251. On November 9, 2010, the Utah Attorney General's Office filed a lawsuit against the Company for illegally marketing Avandia as a new "wonder drug" to combat type 2 diabetes. Utah's Attorney General, Mark Shurtleff, stated that the suit was filed because consumers were misled by the sale and promotion of the diabetic medication:

> Our office will continue to pursue drug companies that misrepresent the effectiveness of their drugs for economic gain and at the expense of the citizens of Utah and the State Medicaid program.

The stated complaint alleges that GSK defrauded Utah out of $7.8 million – representing the

amount the Utah State Medicaid Program spent on Avandia between January 1, 2001 and June 30, 2010.

FACTS CONCERNING WELLBUTRIN

252. A Burroughs Wellcome (now GSK) scientist developed bupropion in 1969. On December 30, 1995, the FDA approved it for sale in the U.S. marketplace as an antidepressant, and the Company marketed it under the name Wellbutrin.

253. In 1986, after a finding that the originally recommended dosage of Wellbutrin had resulted in a significant incidence of seizures, the drug was withdrawn from the marketplace. However, it was re-introduced to the market in 1989 with a maximum recommended dose on the low-end of the original recommendation.

254. In 1997, bupropion was approved by the FDA for use as a smoking cessation aid under the name Zyban.

255. On September 14, 2001, with the support of GSK, Duke University Medical Center published a study finding "Antidepressant Effective For Weight Loss In Women" (the "Duke Study"). The Duke Study stated that:

> A drug approved for the treatment of depression and smoking cessation appears effective for long-term weight loss in obese women, according to researchers at Duke University Medical Center.
>
> The study results, which appear in the Sept. 12 issue of Obesity Research, show that women who took bupropion (trade name Wellbutrin) combined with a 1,600-calorie per day diet lost significantly more weight than women on placebo and the same diet, and those effects were sustained for up to two years, according to Dr. Kishore Gadde, director of obesity clinical trials at Duke and lead investigator of the study.
>
> Approximately 97 million Americans are estimated to be overweight or obese, according to a 1998 report on obesity published by the National Institutes of Health. "Because of the increasing incidence of obesity worldwide, it is vital to identify

new ways of helping people to lose and sustain weight loss," Gadde said. "Obesity carries a tremendous risk of high blood pressure, coronary artery disease, diabetes and a variety of cancers. It is a major health threat."

Fifty non-depressed overweight and obese women between the ages of 24 and 55 were enrolled in the study, the core of which was an eight-week randomized comparison of bupropion with a dummy pill, or placebo, with neither the researcher nor the subject knowing which was the drug and which was the placebo. All women had a body mass index (BMI) between 28.0 and 52.6. A BMI of 25 to 29.9 is considered overweight, while 30 and above is considered obese. Participants were prescribed a 1,600-calorie per day balanced diet.

Women who responded to the drug with demonstrated weight loss after eight weeks continued the same treatment in such a double-blind manner for an additional 16-week "continuation phase." Additional single-blind follow-up treatment was done for a total of two years.

Among the participants who completed the first eight weeks, 67 percent taking bupropion lost more than 5 percent of their baseline body weight, while only 15 percent in the placebo group lost more than 5 percent. During the continuation phase, the 14 bupropion participants who completed 24 weeks achieved an average weight loss of 12.9 percent of their baseline body weight, with nearly 74 percent of the weight loss attributed to a loss of fatty tissue.

"Very low-calorie diets can be quite effective for weight loss in the short term, but the down side is a significant reduction in lean muscle tissue," said Gadde. "It is gratifying to see that most of the weight lost with bupropion treatment came from reduction in fat mass, rather than muscle."

Weight loss can result in loss of bone mineral density, thereby increasing the risk for osteoporosis, a major health risk for women. In this study, there was no change in bone mineral density after 24 weeks of bupropion treatment, the researchers reported.

In a further single-blind follow-up, the 12 bupropion participants who completed two years in the study achieved an average weight loss of 13.6 percent. Bupropion, which is structurally different from other antidepressants, is known to act on the neurotransmitters norepinephrine and dopamine, which have been implicated in the reward and pleasure pathways in the brain. The precise mechanism that makes bupropion effective for weight loss

> is unknown, Gadde said. The weight loss seems be an independent effect of the drug because the participants enrolled in this study were not depressed.
>
> The most commonly reported side effect of bupropion was dry mouth. Although there were no seizures reported in this study, bupropion carries a seizure risk of four in 1,000 people at the maximum dose used in this study, which was 400 milligrams per day. Moreover, it is not recommended for patients with a history of bulimia, anorexia or seizure because the seizure risk may be even higher in those individuals.

256. The Duke Study noted at its conclusion that:

> This study was supported in part by a grant from Glaxo Wellcome (now known as GlaxoSmithKline), to Duke University Medical Center. Further Gadde and Krishnan have served as consultants for Glaxo Wellcome, the manufacturer of bupropion used in the study. Gadde is a member of the Speakers Bureau of GlaxoSmithKline.

257. According to the Dimensions Newsletter dated March 2007, with regards to U.S. Pharmaceuticals, "[t]otal turnover grew by 16% driven by," *inter alia*, Wellbutrin XL sales (+25%).

258. On November 9, 2010 (the last day of the Class Period), the DOJ issued a press release (the "Wellbutrin Indictment"), which stated, in relevant part, that:

> An attorney for a major pharmaceutical company was charged with obstruction and making false statements, the Justice Department announced today. Lauren Stevens of Durham, N.C., was charged with one count of obstructing an official proceeding, one count of concealing and falsifying documents to influence a federal agency, and four counts of making false statements to the Food and Drug Administration (FDA).
>
> The indictment states that in October 2002, the FDA asked for information about the company's promotion of a prescription drug, as part of an inquiry into whether the drug was being promoted for uses that had not been approved by the FDA. Data demonstrating a drug's safety and efficacy for a particular use is required for FDA approval. Federal law prohibits the marketing or promotion of drugs for unapproved – or "off-label" – uses.

The indictment alleges that, in response to the FDA's inquiry, Stevens signed and sent a series of letters from the company to the FDA that falsely denied that the company had promoted the drug for off-label uses, even though she knew, among other things, that the company had sponsored numerous programs where the drug was promoted for unapproved uses. The indictment alleges that Stevens knew that the company had paid numerous physicians to give promotional talks to other physicians that included information about unapproved uses of the drug. According to the indictment, the company paid one such physician to speak at 511 promotional events in 2001-2002 and another physician to speak at 488 such events during that time period.

The indictment also alleges that Stevens did not provide the FDA with slide sets used by the physicians who were paid by the company to promote the drug, even though the FDA had asked for the slide sets and Stevens had previously promised to obtain and provide the FDA with such materials. The indictment alleges that a legal memorandum was prepared for Stevens that set forth the "pros" and "cons" of producing the slide sets to the FDA. According to the indictment, one of the "cons" was that the slide sets would provide "incriminating evidence about potential off-label promotion of [the drug] that may be used against [the company] in this or in a future investigation." Instead of providing the requested slide sets to the government, Stevens represented that the company's responses to the FDA's requests was "final" and "complete."

* * *

The charges were filed in the District of Maryland, where the FDA is located. The case is being prosecuted by the Civil Division's Office of Consumer Litigation and U.S. Attorney's Office for the District of Massachusetts. The case is being investigated by agents from the Office of Inspector General of the Department of Health and Human Services, the FBI, the FDA's Office of Criminal Investigations and the Defense Criminal Investigative Service (DCIS).

"This indictment demonstrates that those who purposely subvert the regulatory functions of the FDA through false statements and misleading information will be held accountable for their deception," stated Dara Corrigan, FDA's Associate Commissioner for Regulatory Affairs. "We commend the efforts of the Department of Justice and the other law enforcement agencies that are vigorously pursuing the prosecution of this matter."

> "Lauren Stevens allegedly misled investigators intentionally and failed to comply with our request for documents," said Susan J. Waddell, Special Agent in Charge of the Department of Health and Human Services Office of Inspector General's Boston region.
>
> "This indictment shows that we will investigate those responsible for unlawful acts done on a company's behalf. When individual employees are identified, they will be held accountable for their illegal activity. Individual employees now know that concealing information from the government, obstructing investigative activity and making false statements to federal investigators will be investigated and prosecuted," said Richard DesLauriers, Special Agent in Charge, FBI, Boston Division.
>
> "This indictment demonstrates that misleading federal officials is a serious offense that will not be tolerated," said Leigh-Alistair Barzey, DCIS Resident Agent in Charge. "DCIS will continue to partner with other federal agencies, such as the FDA, in an effort to protect the DoD's TRICARE health plan, which provides medical care for America's military members and their families."
>
> Each of the obstruction charges carries a maximum penalty of 20 years in prison. Each of the false statement counts carry a maximum penalty of five years in prison. Charges contained in the indictment are simply accusations, and not evidence of guilt.

259. According to a November 10, 2010 article, entitled "Former GSK Lawyer Charged in Bupropion Cover-up," and published by *MedPage Today*, a medical news reporting agency co-developed by MedPage Today and The University of Pennsylvania School of Medicine, Office of Continuing Medical Education:

> The U.S. Department of Justice has charged a former vice president and lawyer at GlaxoSmithKline with trying to cover up evidence that the company was illegally marketing the depression drug bupropion (Wellbutrin) as a weight-loss aid.
>
> Lauren Stevens of Durham, N.C., was charged with one count of obstructing an official proceeding, one count of concealing and falsifying documents to influence a federal agency, and four counts of making false statements to the FDA, according to a press release from the FDA.
>
> The indictment doesn't name the company or the drug, but a lawyer for Stevens confirmed to the Wall Street Journal that

> Stevens was a vice president at GlaxoSmithKline and that the indictment relates to bupropion and an ongoing investigation into the company marketing the depression drug to treat weight loss -- an indication for which it is not approved.
>
> A spokeswoman for GlaxoSmithKline confirmed that Stevens was employed in the company's legal department and that she is now retired.
>
> According to the indictment, the FDA in 2002 asked GlaxoSmithKline for information about the company's promotion of the drug for an unapproved use -- weight loss. The agency asked the drugmaker for all materials related to its bupropion marketing program.
>
> The indictment alleges that Stevens responded to the FDA that GSK was not promoting bupropion off-label, despite having clear evidence that doctors paid by the company, were, in fact, touting the drug for uses not approved by the FDA.
>
> The indictment states that Stevens sent letters to 550 of 2,700 paid speakers for GSK who gave talks on the drug, asking to review their slides. According to the indictment, 40 speakers returned slides to Stevens, and she determined that 28 of the speakers were promoting bupropion off-label.
>
> A Michigan physician had given 488 promotion talks on bupropion to other physicians, in which he repeatedly promoted the drug for off-label uses, including weight loss, according to the indictment. A Vermont doctor did the same thing in 511 presentations on the drug.
>
> The indictment alleges that Stevens withheld the physicians' slides from the FDA, and that a legal memo was prepared for Stevens laying out the "pros" and "cons" of giving the slides to the agency.

260. The indictment accuses the GSK official, Lauren C. Stevens of Durham, N.C., of lying to the Food and Drug Administration in 2003, by writing letters, as associate general counsel, denying that doctors speaking at Company events had promoted Wellbutrin for uses not approved by the agency. Ms. Stevens "made false statements and withheld documents she recognized as incriminating," including slides the FDA had sought during its investigation, the indictment stated.

261. The DOJ's Indictment of Ms. Stevens specifically provides that "other lawyers involved in responding to the FDA provided the memorandum," also outlined in the press release, which stated:

> As you have requested, we are providing a list of the pros and cons of submitting physician presentations on [W-Drug] to FDA . . .

Pros	**Cons**
- Responds to FDA's request 5(a) for copies of all materials presented by individuals identified in response to item 3 and relating to [W-Drug]	- Provides information that appears to promote off-label uses of [W-Drug] for weight loss as well as ADHD, sexual dysfunction, and other unapproved uses
- Potentially garners credibility with FDA	- Potentially demonstrates [K-Corp.]'s lack of control over [K-Corp.] sales representatives
	- Potentially demonstrates [K-Corp.]'s lack of control over physician speakers.
	- Provides incriminating evidence about potential off-label promotion of [W-Drug] that may be used against [K-Corp.] in this or in a future investigation."

U.S. v. Lauren Stevens, Indictment (D. MD. Nov. 9, 2010) (the "Stevens Indictment"), at ¶35.

262. The Stevens Indictment also alleges that, without supplementing GSK's response to the FDA's request, on May 21, 2003, Ms. Stevens informed the FDA that it was the Company's "final" response and falsely stated that the Company had completed its production of information and documents in response to the FDA's October 9, 2002 letter and subsequent January 21, 2003 conference. Id. at ¶36. Stevens further "falsely represent[ed]" that GSK "had been promoting" Wellbutrin consistently with the product label." Ms. Stevens stated:

> a. "In the final analysis, all of the information consistently and clearly points to the same conclusion – [K-Corp.] has not developed, devised, established, or maintained any program or activity to promote, either directly or indirectly, the use of [W-Drug] to achieve weight loss or treat obesity."

> b. "[K-Corp.]'s promotional material and activities for [W-Drug] are consistent with the approved Prescribing Information and the supporting clinical data. All of the documentation and materials we have reviewed and provided to you during the course of this inquiry support this conclusion."

Id. at ¶37.

263. While GSK has not been named in an indictment with regards to allegations concerning the off-label marketing of Wellbutrin as a weight-loss tool, this is another example of the substantial number of investigations by the FDA and DOJ concerning GSK and its misleading business practices prior to and during the Class Period, and GSK's apparent constant tendency to flout FDA rules to serve its own purposes.

CAUSATION

264. The closing price of GSK ADSs on the NYSE on May 8, 2007, the first day of the Class Period, was $57.82. The closing price of GSK ADSs on November 9, 2010, the day the DOJ issued its press release regarding the Wellbutrin indictment, was $39.61. The Defendants/fiduciaries should have "sounded the alarm" to alert Participants of the true risks of investing their retirement savings in GSK ADSs. The Defendants/fiduciaries failed to do so, in violation of their fiduciary duties. Further, *inter alia*, the Defendants/fiduciaries failed to take any action to protect the Plan and the Participants from the foreseeable substantial losses that would follow as the truth about the Cidra plant, the substantial Paxil settlements and Avandia emerged.

265. The Plans suffered millions in losses because a substantial amount of the Plans' assets were imprudently allowed to be put at great risk by Defendants, through investment by the Plans in GSK ADSs during the Class Period, and in breach of Defendants' fiduciary duties.

266. Had Defendants properly discharged their fiduciary duties, including the provision of full and accurate disclosure of material facts concerning investment in GSK ADSs

and divesting the Plans of Company ADSs offered by the Plans when such investment alternative became imprudent, the Plans would not have purchased any Company stock and avoided all of the losses that they suffered through their investment in Company stock.

MISMANAGEMENT OF THE PLANS' ASSETS

267. Pursuant to ERISA § 404(a), 29 U.S.C. § 1104(a), at all times relevant to this Complaint, Defendants had a duty to discharge their duties with respect to the Plans with the care, skill, prudence and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and of like aims.

268. Defendants breached their fiduciary duties in that they should have known the facts alleged above and should have known that assets of the Plans should not have been invested in GSK ADSs during the Class Period.

REMEDIES FOR DEFENDANTS' BREACH OF THEIR FIDUCIARY DUTIES

269. Defendants breached their fiduciary duties in that they knew or recklessly disregarded the facts as alleged above, and therefore knew or recklessly disregarded that the Plans' assets should not have been so heavily invested in Company Stock. As a consequence of Defendants' breaches, the Plans suffered significant losses.

270. ERISA § 502(a)(2), 29 U.S.C. § 1132(a)(2), authorizes the Participants in the Plans to bring a civil action for appropriate relief under ERISA § 409, 29 U.S.C. § 1109. Section 409 requires "any person who is a fiduciary . . . who breaches any of the . . . duties imposed upon fiduciaries . . . to make good to such plan any losses to the plan." Section 409 also authorizes "such other equitable or remedial relief as the court may deem appropriate."

271. With respect to calculation of the losses of the Plans, breaches of fiduciary duty result in a presumption that, but for the breaches of fiduciary duty, the Participants and beneficiaries in the Plans would not have made or maintained their investments in the challenged investment and, where alternative investments were available, that the investments made or maintained in the challenged investment would have instead been made in the most profitable alternative investment available. In this way, the remedy restores the values of the Plans' assets to what they would have been if the Plans had been properly administered.

272. Plaintiffs and the Class are therefore entitled to relief from Defendants in the form of: (1) a monetary payment to the Plans in the amount of the losses to the Plans resulting from the breaches of fiduciary duties alleged above and to be proven at trial based on the principles described above, as provided by ERISA § 409(a), 29 U.S.C. § 1109(a); (2) injunctive and other appropriate equitable relief to remedy the breaches alleged above, as provided by ERISA § 409(a) and 502(a)(2)-(3), 29 U.S.C. § 1109(a) and 1132(a)(2)-(3); (3) reasonable attorneys' fees and expenses, as provided by ERISA § 502(g), 29 U.S.C. § 1132(g), the common fund doctrine, and other applicable law; (4) taxable costs; (5) interests on these amounts, as provided by law; and (6) other legal or equitable relief as may be just and proper.

273. Each Defendant is personally liable and jointly liable for the acts of the other Defendants as a co-fiduciary.

FIRST CLAIM: IMPRUDENT INVESTMENT OF THE PLANS' ASSETS IN GSK ADSs (AGAINST ALL DEFENDANTS)

274. Plaintiffs reallege and incorporate herein by reference the allegations set forth above.

275. GSK ADSs were an imprudent investment option for the Plans because, *inter alia*:

a. the Company has a history of conducting misleading and/or unlawful business activity, both prior to and during the Class Period with regards to, inter alia, GSK's manufacturing, marketing and distributing of prescription medication;

b. the Company's Cidra, Puerto Rico plant was riddled with violations of federal rules and regulations with regards to the operation of that plant, which violations had a large and detrimental effect on, in particular, the Company's sale of Paxil and Paxil CR;

c. the Company had suppressed adverse studies relevant to use of Paxil to treat children and adolescents with depression;

d. the Company had suppressed patient-level meta-analysis of safety data from Avandia trials which demonstrated an estimate of excess risk of ischemic cardiovascular events and other data about the safety of Avandia;

e. the Company's alleged marketing of bupropion (Wellbutrin) as a weight-loss aid spurred a Department of Justice investigation of the Company, including the recent indictment of a Company attorney for "ma[king] false statements and with[holding] documents she recognized as incriminating" from the government;

f. the Company's Paxil and Avandia problems largely contributed to a record charge adjusting earnings of $2.36 billion on or about July 15, 2010 and caused significant reputational damage to GSK;

g. the Company lacked adequate management controls to ensure that an effective quality system existed as required by FDA regulations;

h. because of the foregoing, the Company was at serious risk throughout the Class Period of civil suits and adverse governmental action, including possibly product seizure, injunctions and civil penalties;

i. and the Company's ADSs, as offered by the Fund, were unreasonably risky for retirement savings and a decrease in their value was a near certainty in light of the facts alleged by Plaintiffs.

276. Pursuant to ERISA § 409(a), 29 U.S.C. § 110(a), any fiduciary who breaches any of the responsibilities, obligations or duties imposed by ERISA § 404 shall be personally liable to make good to the Plans any losses to the Plans resulting from each breach and shall be subject to such other equitable and remedial relief as the Court may deem appropriate.

277. Because of the practices described herein, the absence of internal quality controls and other means to assure that the Company's fundamental business operations complied in all respects with applicable rules and regulations, GSK ADSs were not a prudent investment for the individual accounts under the Plans during the Class Period. Defendants knew or should have known that the above problems with, *inter alia*, the Cidra plant, Paxil, Avandia and Wellbutrin, would lead to potential recalls, significant litigation and damages, regulatory problems and reputational damages, resulting in a decrease in the value of the Fund.

278. Pursuant to ERISA § 404, Defendants had a duty to discharge their duties with respect to the Plans solely in the interests of the Participants and for the exclusive purpose of providing benefits to the Participants. Defendants' selection, monitoring, and continuation of the investment alternatives under the Plans were subject to the above-described fiduciary duties. By their continuing to offer GSK ADSs as an investment under the Plans, when GSK's true adverse financial condition was being concealed, Defendants breached each of these fiduciary duties.

279. As a consequence of Defendants' breaches, the Plans suffered losses.

280. Defendants are individually liable to make good to the Plans any losses to the Plans resulting from each breach.

SECOND CLAIM: NEGLIGENT MISREPRESENTATION AND NONDISCLOSURE (AGAINST ALL DEFENDANTS)

281. Plaintiffs reallege and incorporate herein by reference the allegations set forth above.

282. Pursuant to ERISA § 409(a), 29 U.S.C. § 110(a), any fiduciary who breaches any of the responsibilities, obligations or duties imposed by ERISA § 404 shall be personally liable to make good to the Plans any losses to the Plans resulting from each breach and shall be subject to such other equitable and remedial relief as the court may deem appropriate.

283. Pursuant to ERISA § 404, Defendants had a duty to discharge their duties with respect to the Plans solely in the interests of the Participants and for the exclusive purpose of providing benefits to the Participants.

284. Defendants breached these fiduciaries in that they negligently made material misrepresentations and nondisclosures as alleged above in, among other fiduciary communications, the Dimensions Newsletters. Among other things, Defendants negligently failed to disclose to the Participants that, *inter alia*

a. the Company has a history of conducting misleading and/or unlawful business activity, both prior to and during the Class Period with regards to, *inter alia*, GSK's manufacturing, marketing and distributing of prescription medication;

b. the Company's Cidra, Puerto Rico plant was riddled with violations of federal rules and regulations with regards to the operation of that plant, which

violations had a large and detrimental effect on, in particular, the Company's sale of Paxil and Paxil CR;

c. the Company had suppressed adverse studies relevant to use of Paxil to treat children and adolescents with depression;

d. the Company had suppressed patient-level meta-analysis of safety data from Avandia trials which demonstrated an estimate of excess risk of ischemic cardiovascular events and other data about the safety of Avandia;

e. the Company's alleged marketing of bupropion (Wellbutrin) as a weight-loss aid spurred a Department of Justice investigation of the Company, including the recent indictment of a Company attorney for "ma[king] false statements and with[holding] documents she recognized as incriminating" from the government;

f. the Company's Paxil and Avandia problems largely contributed to a record charge adjusting earnings of $2.36 billion on or about July 15, 2010 and caused significant reputational damage to GSK;

g. the Company lacked adequate management controls to ensure that an effective quality system existed as required by FDA regulations;

h. because of the foregoing, the Company was at serious risk throughout the Class Period of civil suits and adverse governmental action, including possibly product seizure, injunctions and civil penalties;

i. and the Company's ADSs, as offered by the Fund, were unreasonably risky for retirement savings and a decrease in their value was a near certainty in light of the facts alleged by Plaintiffs.

285. The Participants relied upon, and are presumed to have rel*ied upon,* Defendants' material misrepresentations and nondisclosures to their detriment.

286. As a consequence of Defendants' material misrepresentations and misleading omissions, the Plans suffered losses.

287. Defendants are individually liable to make good to the Plans any losses to the Plans resulting from each breach.

THIRD CLAIM: DIVIDED LOYALTY
(AGAINST ALL DEFENDANTS)

288. Plaintiffs reallege and incorporate herein by reference the allegations set forth above.

289. Pursuant to ERISA § 409(a), 29 U.S.C. § 110(a), any fiduciary who breaches any of the responsibilities, obligations or duties imposed by ERISA § 404 shall be personally liable to make good to the Plans any losses to the Plans resulting from each breach and shall be subject to such other equitable and remedial relief as the court may deem appropriate.

290. Pursuant to ERISA § 404, Defendants had a duty to discharge their duties with respect to the Plans solely in the interests of the Participants and for the exclusive purpose of providing benefits to the Participants.

291. Defendants breached their fiduciary obligations when they acted in their own interests rather than solely in the interests of the Participants and beneficiaries.

292. As a consequence of these breaches, the Plans suffered losses.

293. Defendants are individually liable to make good to the Plans any losses to the Plans resulting from each breach.

FOURTH CLAIM: MISMANAGEMENT OF THE PLANS' ASSETS (AGAINST ALL DEFENDANTS)

294. Plaintiffs reallege and incorporate herein by reference the allegations set forth above.

295. Pursuant to ERISA § 409(a), 29 U.S.C. § 110(a), any fiduciary who breaches any of the responsibilities, obligations or duties imposed by ERISA § 404 shall be personally liable to make good to the Plans any losses to the Plans resulting from each breach and shall be subject to such other equitable and remedial relief as the court may deem appropriate.

296. Pursuant to ERISA § 404(a)(1), 29 U.S.C. § 1104(a)(1), Defendants were required to discharge their duties with respect to the Plans solely in the interests of the Participants with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and of like aims.

297. Defendants breached these duties in that the Plans invested in GSK ADSs when the price of GSK ADSs was artificially inflated, and when GSK ADSs were imprudent for Participants' retirement savings.

298. As a consequence of these breaches, the Plans suffered losses.

299. Defendants are individually liable to make good to the Plans any losses to the Plans resulting from each breach.

FIFTH CLAIM: BREACH OF THE DUTY TO PROPERLY APPOINT, MONITOR AND INFORM THE COMMITTEE AND MEMBERS OF THE COMMITTEE (AGAINST THE DIRECTOR DEFENDANTS ONLY)

300. Plaintiffs reallege and incorporate herein by reference the allegations set forth above.

301. The Director Defendants had the duty and responsibility to properly appoint, monitor and inform the members of the TIC and/or other persons who exercised day-to-day responsibility for the management and administration of the Plans and their assets.

302. The Director Defendants failed to properly appoint, monitor and inform such persons in that the Director Defendants failed to adequately inform such persons about the true financial and operating condition of the Company or, alternatively, the Director Defendants did adequately inform such persons of the true financial and operating condition of the Company (including the financial and operating problems being experienced by GSK during the Class Period identified herein), but nonetheless continued to allow such persons to offer GSK common stock as an investment option under the Plans even though the market price of GSK common stock was artificially inflated and even though GSK common stock was not a prudent investment for Participants' retirement accounts under the Plans.

303. As a consequence of these breaches, the Plans suffered losses.

304. The Director Defendants are individually liable to make good to the Plans any losses to the Plans resulting from each breach.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for:

A. Actual damages in the amount of any losses the Plans suffered, with such losses to be allocated among the Participants' individual accounts in proportion to the accounts' losses;

B. Costs pursuant to 29 U.S.C. § 1132(g); and

C. Attorneys' fees pursuant to 29 U.S.C. § 1132(g) and the common fund doctrine.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: November 22, 2010

STULL, STULL & BRODY

By: _____

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CERTIFICATE OF SERVICE

I, Michael J. Klein, hereby certify that I caused the annexed document (Consolidated Amended Complaint For Violations Of The Employee Retirement Income Security Act) to be served upon the following counsel for all Defendants by email on this 22nd day of November, 2010:

- Jeremy P. Blumenfeld (jblumenfeld@morganlewis.com)
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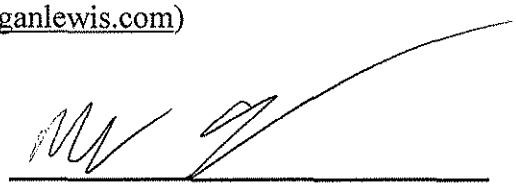

Michael J. Klein
Stull, Stull & Brody